

U.S. DEPARTMENT OF COMMERCE PATENT AND TRADEMARK OFFICE		ATTORNEY'S DOCKET NUMBER STAHL1
TRANSMITTAL LETTER TO THE UNITED STATES DESIGNATED/ELECTED OFFICE (DO/EO/US) CONCERNING A FILING UNDER 35 U.S.C. 371		U.S. APPLICATION NO. (If known, see 37 CFR 1.5) 09/623425
INTERNATIONAL APPLICATION NO. PCT/DK99/00108	INTERNATIONAL FILING DATE 3 March 1999	PRIORITY CLAIMED 4 March 1998
TITLE OF INVENTION A COATED CHEWING GUM, A METHOD FOR PREPARATION THEREOF ...		
APPLICANT(S) FOR DO/EO/US B. STAHL		
<p>Applicant herewith submits to the United States Designated/Elected Office (DO/EO/US) the following items and other information:</p> <ol style="list-style-type: none"> <input checked="" type="checkbox"/> This is a FIRST submission of items concerning a filing under 35 U.S.C. 371. <input type="checkbox"/> This is a SECOND or SUBSEQUENT submission of items concerning a filing under 35 U.S.C. 371. <input checked="" type="checkbox"/> This is an express request to begin national examination procedures (35 U.S.C. 371(f)) at any time rather than delay examination until the expiration of the applicable time limit set in 35 U.S.C. 371(b) and PCT Articles 22 and 39(1). <input checked="" type="checkbox"/> A proper Demand for International Preliminary Examination was made by the 19th month from the earliest claimed priority date. <input checked="" type="checkbox"/> A copy of the International Application as filed (35 U.S.C. 371(c)(2)) <ol style="list-style-type: none"> <input type="checkbox"/> is transmitted herewith (required only if not transmitted by the International Bureau). <input checked="" type="checkbox"/> has been transmitted by the International Bureau. <input type="checkbox"/> is not required, as the application was filed in the United States Receiving Office (RO/US). <input type="checkbox"/> A translation of the International Application into English (35 U.S.C. 371(c)(2)). <input checked="" type="checkbox"/> Amendments to the claims of the International Application under PCT Article 19 (35 U.S.C. 371(c)(3)) <ol style="list-style-type: none"> <input type="checkbox"/> are transmitted herewith (required only if not transmitted by the International Bureau) <input type="checkbox"/> have been transmitted by the International Bureau. <input type="checkbox"/> have not been made; however, the time limit for making such amendments has NOT expired. <input checked="" type="checkbox"/> have not been made and will not be made. <input type="checkbox"/> A translation of the amendments to the claims under PCT Article 19 (35 U.S.C. 371(c)(3)). <input type="checkbox"/> An oath or declaration of the inventor(s) (35 U.S.C. 371(c)(4)). <input type="checkbox"/> A translation of the annexes to the International Preliminary Examination Report under PCT Article 36 (35 U.S.C. 371(c)(5)). <p>Items 11. to 16. below concern document(s) or information included:</p> <ol style="list-style-type: none"> <input type="checkbox"/> An Information Disclosure Statement under 37 CFR 1.97 and 1.98. <input type="checkbox"/> An Assignment document for recording. A separate cover sheet in compliance with 37 CFR 3.28 and 3.31 is included. <input checked="" type="checkbox"/> A FIRST preliminary amendment. <input type="checkbox"/> A SECOND or SUBSEQUENT preliminary amendment. <input type="checkbox"/> A substitute specification. <input type="checkbox"/> A change of power of attorney and/or address letter. <input checked="" type="checkbox"/> Other items or information: <ul style="list-style-type: none"> <input checked="" type="checkbox"/> Courtesy copy of the International Application as filed. <input checked="" type="checkbox"/> Courtesy copy of the first page of the International Publication (WO 99/44436). <input checked="" type="checkbox"/> Courtesy copy of the International Preliminary Examination Report with annexes containing claims 1-30 to be substituted for the original claims for examination in this case. <input checked="" type="checkbox"/> Formal drawings, 14 sheets, Figures 1-14. <input checked="" type="checkbox"/> Courtesy Copy of the International Search Report. 		

Form PTO-1390 (as slightly revised by Browdy and Neimark)

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IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re Application of:)	Art Unit:
B. STAHL)	
)	
IA No.: PCT/DK99/00108)	
)	Washington, D.C.
IA Filed: 3 March 1999)	
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U.S. App. No.:)	
(Not Yet Assigned))	
)	September 5, 2000
National Filing Date:)	
(Not Yet Received))	
)	
For: A COATED CHEWING GUM, ...)	Docket No.: STAHL1

PRELIMINARY AMENDMENT

Honorable Commissioner of Patents and Trademarks
Washington, D.C. 20231

Sir:

Contemporaneous with the filing of this case and
prior to calculation of the filing fee, kindly amend as
follows:

IN THE CLAIMS

In claim 6, change "any of claims 1-5" to --claim
1--.

In claim 7, change "any of claims 1-6" to --claim
1--.

In claim 10, change "any of claims 1-9" to --claim
1--.

In claim 11, change "any of the preceding claims" to
--claim 1--.

In claim 16, change "any of the preceding claims" to
--claim 1--.

In claim 17, change "any of the preceding claim[s]"
to --claim--.

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In claim 18, change "any of claims 1-17" to --claim 1--.

In claim 19, change "any of the preceding claims" to --claim 1--.

In claim 21, change "any of the preceding claims" to --claim 1--.

In claim 23, change "any of claims 1-22" to --claim 1--.

In claim 26, change "any of claims 23-25" to --claim 23--.

In claim 27, change "any of claims 23-26" to --claim 23--.

In claims 1, 2, 3, 12, 13, 14, 15, 17, 19, 20, 22 and 25 replace "among" with --group consisting of--.

In claim 4, delete ", preferable... 25%".

In claim 5, delete ", such as ... 2-6%".

In claim 8, delete ", such as ... 1 mm".

In claim 9, delete ", such as 1 mm".

In claim 10, delete "e.g. ... raspberry".

In claim 15, delete "[zinc compound],".

In claim 20, delete "such as ... aloe vera" and "such as ... tomato".

In claim 23, delete "in a manner known per se" (all occurrences).

In claim 26, delete ", preferably ... increments".

In claim 27, delete ", preferably ... increment(s)".

Please cancel claims 28-30.

If, inadvertently, a proper multiple dependent claim has not been amended to reduce it to single dependency, please amend it to be dependent solely on the first-mentioned claim,

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or, if that is not possible, please cancel the claim and
notify the undersigned.

REMARKS

The above amendments to the claims are being made in order to eliminate any properly multiply dependent claims, for the purpose of reducing the filing fee and also to place the application in better condition for examination. Please enter this amendment prior to calculation of the filing fee in this case.

Favorable consideration and allowance are earnestly solicited.

Respectfully submitted,
BROWDY AND NEIMARK, P.L.L.C.
Attorneys for Applicant

By: Iver P. Cooper
Registration No. 28,005

IPC:edg
Telephone No.: (202) 628-5197
Facsimile No.: (202) 737-3528
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A Coated Chewing Gum, a Method for Preparation thereof and the Use of One or
More Active Substance(s) in Solid Form

Technical Field

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The present invention relates to a coated chewing gum comprising a core of chewing gum and a coating comprising a coating material as well as one or more active substance(s) in solid form. Furthermore, the invention relates to a method for the preparation of a coated chewing gum and the use of one or more active substance(s) in
10 solid form in the coating of a coated chewing gum.

Technical Background

Coated chewing gum is prepared by coating a core of chewing gum with a number of
15 layers of coating. The coating most often takes place in rotating coating kettles in which cores of chewing gum are rotated and coating suspension is applied in small portions that disperse evenly over the surfaces of the cores. Subsequently, the coated cores are dried by means of air.

20 These coating operations may be applied in up to approx. 90 increments until the preferred coating thickness is obtained, and the product has the preferred measures and the preferred weight.

The coating suspension is often an aqueous solution of a sugar or the like applied at
25 an elevated temperature to ease the coating process.

In order to provide a fast flavour onset, often one or more flavour(s) is/are applied and possibly other active substances between the applications of the coating suspension. The active substance(s) is/are added in liquid form in one or more increment(s).

30

A chewing gum with a completed coating is normally finally treated with a surface layer of a wax or the like.

The tablets with a completed coating are then subjected to a hardening process during the following approx. 8 weeks. Sugar alcohols such as sorbitol and xylitol thus form crystals whereby the chewing gum obtains a harder and a "crunchy" coating. The crystallisation process also provides a more porous coating structure. Thus, a migration
5 of water, moisture and flavour takes place through the formed micro channels.

This causes the chewing gum to gradually lose its flavour, ethereal oils, if any, are oxidised, and the chewing gum loses moisture and gets harder.

10 Furthermore, the use of active substances in liquid form in the coating layers has the disadvantage that some of the active substances are lost to the surroundings during the coating process.

It has now been found that by using active substances in solid form in the coating
15 layers of conventional chewing gum, an increased stability of the active substance is obtained. Furthermore, a faster onset of the effect is achieved, and by using flavour in solid form, a longer lasting explosion of taste compared with chewing gum coated with a liquid flavour. Finally, according to the invention, a more environmentally desirable manufacturing process is obtained since the use of an active substance in
20 solid form causes less evaporation of volatile substances.

Disclosure of the Invention

Thus, the invention relates to a coated chewing gum comprising a core of chewing
25 gum and a coating which comprises a coating material, and one or more active substance(s), which chewing gum is characterised in that the active substance(s) is/are added in solid form.

Furthermore, the invention relates to a method for the preparation of a coated
30 chewing gum according to the invention, which method is characterised in that it comprises the following steps:

- 1) preparation of a core of chewing gum in a manner known *per se*,

- 2) preparation of a coating suspension, also in a manner known *per se*,
 - 3) repeated applications of the coating suspension onto the cores of chewing gum also in a manner known *per se*, preferable at a temperature in the interval 30-90°C, preferably 35-75°C,
 - 4) Applying on the coating of one or more active substance(s) in solid form in one or more increment(s) after the application of the coating suspension, and optionally repeating step 3) and 4)
 - 5) optionally, application of one or more liquid active substance(s) in one or more increment(s) between the applications of the coating suspension,
 - 6) optionally, finally application of a surface layer.
- Applying of the solid active substance(s) is/are preferable performed without drying of the coating suspension in order to enable adherence of a substantial amount of the substance(s) in solid form to the coating. The drying time for the coating suspension depends on the specific coating formulation, however, the active substance(s) is/are added to the coated chewing gum substantially without delay after the coating processes are finished. If desired, the coated chewing gum may be wetted before adding the active substance(s) in solid form in case the coating has been allowed to dry for too long time whereby the coated chewing gum is no longer sticky.
- The coating process may be repeated as many times as needed in order to obtain the desired thickness of the coating. In the coating process, the active substance(s) in solid form may be added between one or more of the ordinary coating processes. The last layer of the coating process may also include the active substance(s) in solid form. It is also within the present invention to use different active substances in solid form in the same coating layer or use one active substance in one layer, and a second active substance in another layer. Such combinations of active substances may be flavour and high potent sweeteners or a medicament together with an substance decreasing an undesirable taste of the medicament.

As the active substance(s) is/are located in the outer part of the coating, the active substance(s) is/are exposed to the consumer within a short period of chewing.

Accordingly, in a further embodiment, the invention relates to the use of one or more active substance(s) in solid form in the coating of a coated chewing gum in order to

5 obtain a fast onset of the effect.

A further advantage of the admixture of the active substance(s) in solid form is that the solid form is more resistant to decomposition. Accordingly, the invention also relates to the use of one or more active substance(s) in solid form in the coating of a

10 coated chewing gum in order to obtain a better stability of the active substance(s).

Finally, the invention relates to the use of one or more active substance(s) in solid form in the coating of a coated chewing gum in order to obtain an increased effect of the active substance(s) in all chewing phases.

15

Brief Description of the Drawing

The invention is further illustrated by means of the drawing, in which

20 Fig. 1 shows the release of flavour as a function of time by using menthol/-anethol/eucalyptus flavour in encapsulated form and liquid form, respectively,

Fig. 2 shows the release of flavour as a function of time by using the same amount of eucalyptus/anethol/menthol flavour in encapsulated form and liquid form, respectively,

25 Fig. 3 shows the release of flavour as a function of time by using liquid eucalyptus/anethol/menthol flavour and with and without encapsulated menthol,

Fig. 4 shows the stability of chewing gum with apple/cinnamon flavour with encapsulated and non-encapsulated aspartame, respectively, in suspension form in the

30 coating,

Fig. 5 shows a flavour profile in the initial phase of chewing gum with fruit flavour (lemon/orange/mango) with and without encapsulated citric acid in the coating,

Fig. 6 shows a flavour profile in the initial phase of a chewing gum with fruit flavour (lemon/orange/mango) with and without encapsulated "cooling agent" in the coating,

Fig. 7 shows the same in the intermediate phase,

5

Fig. 8 shows the same in the end phase,

Fig. 9 shows a flavour profile in the initial phase of chewing gum with menthol/-anethol/eucalyptus flavour and with encapsulated thyme extract in the coating,

10

Fig. 10 shows the same in the intermediate phase,

Fig. 11 shows the same in the end phase,

15 Fig. 12 shows a flavour profile in the initial phase of chewing gum with menthol/-anethol/eucalyptus flavour and with encapsulated extract of black pepper in the coating,

Fig. 13 shows the same in the intermediate phase, and

20

Fig. 14 shows the same in the end phase.

The scope of the invention will appear from the detailed description below. However, it should be understood that the detailed description and the specific examples, while

25 indicating preferred embodiments of the invention, are given by way of illustration only, since various changes and modifications within the scope of the invention will become apparent for those skilled in the art from the detailed description.

Detailed Description of the Invention

30

The active substances are selected among flavours, acids, salts, high potent sweeteners, and functional substances.

Aromas, which may be incorporated into the chewing gum according to the invention, are selected among natural, naturally identical or synthetic flavours, as well as plant extracts. Examples of applicable flavours are for example peppermint, periwinkle, eucalyptus, spearmint, anethol, menthol, powdered anise, and fruit flavours such as
5 orange, lemon, mango, pineapple, lime, strawberry, cherry, black currant, blueberry, raspberry, wild berry, cranberry, apple, pear, banana, prune, and plum flavour, etc.

The plant extracts which may be applied instead of or together with one or more of the above-mentioned flavour(s) are preferably selected among extracts of liquorice,
10 coffee, tea, herbs such as sage, thyme, basil, bergamot, balm, valerian, camomile, lavender, aloe vera, and spices such as pepper, cinnamon, capsicum, paprika, tarragon, fennel, mustard, dill, caraway, parsley, tomato, etc.

The use of plant extracts in coated chewing gum provides the possibility of preparing
15 novel combinations of flavour and new flavour experiences.

In a preferred embodiment of the invention the active substance(s) is/are a natural vegetable flavouring agent such as fruit and herbs. Accordingly the substance may be selected among coconut, grape fruit, orange, lime, lemon, mandarin, pineapple,
20 strawberry, raspberry, mango, passion fruit, kiwi, apple, pear, peach, apricot, cherry, pineapple, grapes, banana, cranberry, blueberry, black currant, red currant, gooseberry, and lingonberry, thyme, basil, valerian, fennel, parsley, camomile, tarragon, lavender, dill, cumin, bergamot, sage, aloe vera, spearmint, peppermint, eucalyptus and mixtures thereof.

25

It is furthermore an advantage that the natural flavouring agent is dried. A dried agent may have a more intense flavour and may further increase the stability of the flavour because many of the notes of the taste are still present in the more or less intact cells of the fruit or herb. The limited content of water is also an important factor with
30 respect to stability.

In a further aspect, the water content of the natural flavouring agent is less than 75% by weight, such as less than 60%, preferable less than 40%, more preferred less than 30%, such as less than 25%. However, in situations where a less water content is

desired (for stability reasons or with respect to have an increased flavour sensation), the water content of the natural flavouring agent is less than 20% by weight, such as less than 15%, more preferred less than 10% such as between 1.5-7%, more preferred between 2-6%.

5

In a preferred embodiment, the natural flavouring agent is freeze-dried.

The natural flavouring agent in solid form may be in the form of a powder, slices or pieces, or combinations thereof. When a natural vegetable flavour is used, it is

10 generally accepted or even desired that a feeling of small pieces of the flavour agent be recognised by the consumer in the chewing process. Accordingly, the natural flavouring agent may be in a form where the particle size is up to 3mm or even more. However smaller pieces are preferred and in a further aspect, the particle size is less than 3mm, such as less than 2mm, more preferred less than 1mm, calculated as the
15 longest dimension of the particle.

In other situations it may be an advantage to have different sizes of the particles and an example is wherein the natural flavouring agent is in a form where the particle size is from about 3 μ to 2mm, such as from 4 μ to 1mm. However, the skilled person may
20 select any combination dependent on the desired final properties of the coated chewing gum.

As seeds from fruits may have a special flavour, the natural flavouring agent may comprise seeds from a fruit e.g. from strawberry, blackberry and raspberry, and which
25 seeds are substantially intact.

In a still further aspect of the invention, the natural vegetable flavouring agent also provides the gum formulation with natural colour. With seeds of a vegetable or fruit flavouring agents such as strawberry and/or orange, it has been possible to obtain a
30 marbling colouring of the chewing gum as well as a uniform colouring. Accordingly, in a further aspect of the invention, the active substance in solid form may be a colouring agent.

Various acids may also be applied as active substances, such as citric acid, malic acid, tartaric acid, lactic acid, and ascorbic acid or any other acid allowed in food and which is suitable. These may most conveniently be applied together with chewing gum with fruit flavour in order to obtain an improved freshness during the first phase of the

5 chewing period.

Furthermore, according to the invention, instead of or together with one or more of the above-mentioned active substance(s), salts may be applied, such as sodium chloride, potassium chloride, ammonium chloride, sodium bicarbonate, and carbamide.

10 Hereby an improved chewing gum taste during the initial chewing period is obtained, and in case of sodium bicarbonate and carbamide also an improved dental care effect.

In order to obtain a sweet taste during the initial chewing period, together with or instead of one or more of the above-mentioned active substance(s) sweeteners may

15 be incorporated in the coating, preferably highly potent sweeteners. Especially suitable sweeteners are e.g. aspartame, acesulfame K, saccharin, cyclamate, neohesperidine, thaumatin, glycyrrhizin, and salts thereof, monellin, sucrolase, and alitame.

Finally, in order to obtain a specific effect together with or instead of one or more of

20 the above-mentioned active substance(s), one or more functional substance(s) can be incorporated in the coating such as vitamins and nutrients, "cooling agents", flavour enhancers, enzymes, agents for care and treatment of the oral cavity, antiseptic agents, pharmaceuticals and herbal medicine.

25 "Cooling agents" and flavour enhancers are substances manufactured by so-called "flavour houses", and which substances are also known as "flavour enhancer", "cooling flavour", "physcol", "optacool", and the like. They are applied in order to make the taste stronger and fresh.

30 Examples of cooling agents are e.g. lactic acid menthyl ester, disclosed in EP 0794169 A1, mono menthylsuccinate, and salts thereof, disclosed in WO97/07771, and 4-(1-menthoxymenthyl)-2-phenyl-1,3-dioxolan and derivatives thereof, disclosed in US 5,545,424.

Among the vitamins and the nutrients that may be incorporated in the chewing gum according to the invention special mention can be made, without limitation, of the vitamins A, B₁, B₂, B₅, B₆, B₁₂, D₃, E, K, folic acid, niacin, biotin, β -carotene, ascorbic acid, and salts thereof, amino acids, glycerophosphates, minerals in the form of salts, 5 complexes and compounds containing calcium, phosphorus, magnesium, iron, zinc, copper, iodine, manganese, chromium, selenium, molybdenum, potassium, sodium, or cobalt and ubiquinon.

Among agents for the care and treatment of the oral cavity, special mention may be 10 made of hydrogen peroxide, carbamide and carbamide releasing compounds, CPP (caseinphosphopeptide), fluorine compounds such as sodium fluoride, sodium monofluorophosphate, and stannofluoride, arginine, zinc compounds, strontium chloride and potassium nitrate.

15 Among antiseptic agents, special mention may be made of guanidine and biguanidine, such as chlorhexidine acetate, quaternary ammonium compounds such as benzalkonium chloride, cetylpyridinium chloride, and cetrimide, phenols such as tymol, triclosan, parachlorophenol, and cresol, hexachlorophen as well as salicylanilide compounds.

20 Enzymes may also be incorporated in the chewing gum according to the invention, e.g. papain, trypsin, amyloglucosidase, lactase, glucoseoxidase, streptokinase, streptodornase, dextranase, and mutanase.

25 Among pharmaceuticals, special mention may be made of caffeine, salicylic acid, and derivatives thereof, such as acetylsalicylic acid, choline salicylate, and magnesium salicylate, paracetamol, salts of pentazocine, buprenorphine, and buprenorphine hydrochloride, codeine hydrochloride and phosphate, morphine and salts thereof, methadone hydrochloride, ketobemidone, β blockers, calcium antagonists, verapamil 30 hydrochloride, verapamil, nifedipine, nitroglycerin, erythrityl tetranitrate, strychnine and salts thereof, lidocaine, tetracaine hydrochloride, etorphine hydrochloride, atropine, insulin, alfa-amylase, polypeptides such as oxytocin, gonadorelin, and LHRH, desmopressin acetate (DDAVP), isoxsuprine hydrochloride, ergotamine compounds, chloroquine phosphate and sulfate, isosorbide, demoxytocin, heparin, lupeol,

sucralfate and salts thereof, nicotine and salts and derivatives thereof, lobeline, cinnarizine, dimenhydrinate, difenhydramine, cyclizine, scopolamine, miconazole, nystatin, metronidazole, hydrocortisone, astemizole, benzocaine, glibenglamide, onsaedantronum, acyclovir, sumatriptan, tropisetron, pizotifen, cisapride,

- 5 domperidone, itraconazole, omeprazole, terfenadine, fluconazole, naratriptan, zolmriptan, rizatriptan, eletriptan, almotriptan, sildenafil, tolfenamic acid, tramadol, cetirzine, and loratidine.

- Among herbal medicine special mention may be of ginkgo biloba, ginseng, saw
10 palmetto, stevia, ginger, propolis, echinacea, St. John's Wort, Siberian ginseng, guarana, and garlic in the form of drugs, extracts or in purified form.

- Furthermore, it is possible by means of the present invention to add substances, which cannot resist the thermal and mechanical influences that normally occur during
15 the manufacturing of cores of chewing gum, such substances being certain vitamins, enzymes, and pharmaceuticals.

- The active substance(s) is/are added in the form of dry active substance, preferably spray-dried active substance, or in the form of encapsulated active substance. In a
20 preferred embodiment of the present invention, the active substance is present in an encapsulated form. The active substance is preferably present in the form of a powder with particles having a size of 3-300 μm .

- The use of encapsulated active substance provides a larger stability of the substance,
25 and the active substance migrates very slowly to the surface of the coated chewing gum. Furthermore, the contact of the encapsulated active substances with the air is limited, whereby possible oxidation processes take place very slowly. The latter are of particular significance in connection with flavours, especially in the form of ethereal oils, such as peppermint, lemon, lime, and orange.

30

In addition, by encapsulating the active substance, it is achieved that its reaction with other substances is prevented, substances like e.g. sodium bicarbonate with acid and aspartame with aldehyde-containing flavours, and especially in case of substances with an unpleasant taste, e.g. certain pharmaceuticals, the taste may be camouflaged.

In addition, it has been found that by chewing chewing gum that is coated with encapsulated flavour, not only a strong taste explosion is achieved, but also an enhanced taste in all chewing phases. The latter is due to the fact that flavour

5 capsules from the coating layer of the chewing gum are opened both during the initial chewing and in following chewing period.

Furthermore, using an encapsulated active substance may prevent a discoloration of the coating, e.g. plant extracts such as thyme or black pepper. Finally, it may be

10 desirable to prevent water-solubility, e.g. in connection with the use of acids and salts as the active substance.

When an encapsulated active substance is used, conventionally used encapsulation agents are used as the encapsulation agent, for instance, but without limitation, fatty

15 substances, waxes, gelatin, gum arabic, starch, cellulose, cellulose derivatives, shellac, polyvinyl acetate (PVA), polyethylene (PE), casein, zein, B cyclodextrine, silica, yeast cells, and a mixture of the above encapsulation agents. Preferred encapsulation agents comprise fatty substances such as hydrogenated soy bean, cottonseed, coconut, sunflower, palm kernel, rapeseed, and ricinus oil, or waxes such
20 as bees' wax, candelilla wax, carnauba wax, paraffin wax, and polyethylene wax, etc. Especially preferred is the use of a mixture of hydrogenated rape oil and carnauba wax.

Encapsulated flavour and methods for encapsulation are known from, e.g., EP O 170

25 752 A2, EP O 453 397 A1, EP O 455 598 B1, and US 4,386,106.

In a particularly preferred embodiment of the coated chewing gum according to the present invention, the coating also comprises besides the coating material as well as one or more active substance(s) in solid form, one or more liquid active substance(s).

30 This provides a larger flexibility of the process of chewing gum manufacture, and, when encapsulated active substance is concerned, a reduction in costs, since the encapsulation makes the process more expensive, and it is thus reserved for only the most sensitive active substances.

In one embodiment of the invention, the coating suspension comprises an aqueous solution of a sugar, a sugar alcohol, an artificial sweetener or mixtures thereof, preferably an aqueous solution of saccharose, dextrose, sorbitol, xylitol, tagatose, mannitol, maltitol, isomalt, aspartame, acesulfame K, saccharin, cyclamate, thalline, 5 and neohesperidine.

The coating suspension is applied in approx. 2 to 90 increment(s), preferably in approx. 30-60 increments to achieve a uniform coating with a suitable thickness.

10 The active substance(s) is/are applied by sprinkling or by blowing the substances into the rotating kettles a number of times such as from 1 to 10 times between the dosages of the coating suspension, preferably approx. 1 to 4 times to achieve a suitable effect.

15 The following is a general description of the preparation of chewing gum.

Preparation of Chewing Gum

The preparation process comprises the following:

20

Mixing of conventional chewing gum components in kneading kettles (mixers) with strong horizontally placed Z-shaped arms, which processes the raw materials and produces a homogeneous gum mass.

25 The kneading kettles are heated to a temperature of 30-80°C, typically approx. 45°C. The mixing process starts with gum base quantities that have been weighed out, and the processing of these lasts for 1-20 minutes, typically approx. 10 minutes. Then one or more sweetener(s) in powder form or in liquid form is/are added. The dosage of sweeteners and the following processing last from 1 to 20 minutes, typically approx. 30 7 minutes.

Then the flavours and the remaining components are added and kneaded for a further 1 to 10 minutes, typically approx. 5 minutes. The admixture of flavours and the remaining components may also take place in the beginning of the kneading process,

i.e. before the admixture of the sweeteners. It is also possible to add flavours in two or more portions during the kneading process.

When the kneading is completed, the kneading kettle is tipped, and the gum mass is
5 taken out into carts, onto trays or the like.

The next process is the forming of the chewing gum. Before the forming can take place, the chewing gum mass, however, must be cooled. When taken out, the chewing gum mass has a temperature of 50-70°C, and in order to form the chewing
10 gum, the temperature must be reduced to 30-45°C. The cooling of the chewing gum either takes place by storing the chewing gum mass in carts or on trays for quite a long time or by transporting a thin chewing gum carpet through a cooling tunnel.

The forming of the chewing gum may take place by extrusion through a specially
15 formed nozzle, or the chewing gum may be formed after extrusion by means of rollers, punching machines, tentering wheels, and the like.

The chewing gum may be formed into cores, sticks, balls, cubes, cylinders, and many other shapes.
20

In order to prevent the chewing gum from sticking to the rollers and other tools, the chewing gum is frequently powdered with a powder, which may consist of i.a. icing sugar, talc, corn flour, and the like.

25 The formed chewing gum can be cooled immediately to room temperature in a cooling tunnel and be packed (especially in case of bubble gum and soft bubble gum), or the cooling may take place on trays at the store for semimanufactured products at a controlled temperature and moisture.

30 The formed and cooled chewing gum is then treated by means coating and polishing processes before the packing.

Coating and Polishing of Cores of Chewing Gum

The coating of cores takes place in tilted, round or horizontally placed cylindrical coating kettles that rotate during the whole process. The coating kettles are made
5 from copper, stainless steel or fiberglass-reinforced polyester, and are often equipped with a piping system that supplies and exhausts air and doses the coating suspension.

The coating process may take place as follows:

Cores of chewing put into movement in rotating coating kettles are added to the
10 coating suspension in small portions that disperse evenly over the surfaces of the cores after a short or long smoothing out time. (The smoothing out time is the period of time during which the suspension disperses over the cores, approx. 10-90 seconds, preferably approx. 30-60 seconds). Afterwards the cores are dried by means of air. The operation is repeated up to 90 times, preferably approx. 30-40 times, until the
15 cores are completely covered and have the preferred measure and the preferred weight.

In order to ease the coating process of chewing gum, a suspension is used which is heated up to 90°C, preferable up to about 75°C, and air which is heated up to at least
20 35°C such as about 40°C.

Between the dosages of the coating suspension, one or more active substance(s) in solid form is/are added in one or more increment(s) in order to provide the chewing gum with a fast effect, e.g. flavour release during the chewing. It is an important
25 aspect of the invention that the drying period is extended to after applying the active substances. When the active substances are added just after the coating process is completed, the coating suspension is still soft and the active substances may be more or less embedded in the coating in the solid form. The skilled person will be able to estimate or to establish by a simple test when the active substance should be added
30 for obtaining a sufficient adherence of the active ingredient to the coating.

As appears from the Examples, the drying period is 0 seconds, however, drying periods up to 50 seconds such as up to 25 seconds are within the present invention and even longer periods may be acceptable depending on the drying properties of the

coating suspension, the particle size of the active substance as well as whether it is desired that the active substance should be fully embedded in the coating or should form a superficial layer on the coating.

- 5 Furthermore, between the dosages of the coating suspension and the addition of one or more active substance(s) in solid form, one or more active substance(s) in liquid form may be added.

- In order to achieve a neat and smooth surface of the chewing gum tablets with the
- 10 completed coating, these may subsequently be subjected to a polishing. The polishing also takes place in rotating coating kettles in which a polishing suspension or a polishing powder is added to the coated cores in one or more portion(s). The polishing suspension often consists of wax, emulsifier, shellac, gum arabic, water, etc. The polishing powder often consists of wax only, or of wax mixed with emulsifier, gum
 - 15 arabic or talc, etc.

The present invention is further illustrated below by means of some examples.

Examples

As a starting point, partly sugar-containing, partly sugar-free cores of chewing gum
5 are used which are rolled out into sheets by means of stamping rollers, i.e. coherent
sheets of cores of chewing gum which have a weight of approx. 0.9g/piece.

A coating kettle DRIA 1200, supplied by Driam Metallprodukt GmbH, Germany, is
used for the coating of the above-mentioned cores. DRIA 1200 is a horizontally placed
10 and cylindrical kettle intended for the coating of 50kg of chewing gum cores. The
equipment has computer controlling of the amount of dosages of liquid and solid
substances as well as controlling of the smoothing out times, the drying times, air
quantities, the temperature of the drying air, and the airflow direction. For dosage of
an active substance in a solid form, a pneumatic conveyor having a dispersing arm
15 which ensures an even dispersion of the powder over all the tablets. The coating
kettle can be set at various velocities from 1 to 15 rpm.

During the coating process, 50kg of chewing gum cores are filled into the coating
kettle that can be set to a rotation of 8 rpm. During this rotation, the cores of chewing
20 gum are separated from each other. Drying air is applied to the equipment, and surplus
talc, which has been added during the rolling out of the cores of chewing gum, is
removed. This separation and blowing through of air last for approx. 5 minutes.

Then the rotation speed of the coating kettle is increased to 11 rpm, and the first
25 dosage of the coating suspension may take place.

It is also possible to use small (2kg) or large (100kg) tilted, round coating kettles and
sprinkle active substance in solid form manually in 1-10 increment(s) between the
dosages of the coating suspension. Dosage of active substance in more increments
30 ensures an even dispersion of the powder over all the cores of chewing gum.

For the coating of sugar-containing cores of chewing gum, a saccharose suspension
was used in the following examples, and a sorbitol suspension was used for the
coating of sugar-free cores.

In the following embodiments, the coating suspension had the following composition:

1. Saccharose suspension

5

Sugar juice (70%)	94.45 %
Water	4.68 %
Gelatine (Bloom value 120-160)	0.87 %

10	Total	100.00 %
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2. Sorbitol suspension

15

Sorbitol liquid/neosorb 70/02	97.86 %
Water	1.59 %
Titanium dioxide	0.55 %

Total	100.00 %
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20 The Examples 1, 2, and 3, shows conventional coating of sugar-containing and sugar-free cores of chewing gum, respectively.

Example 1

Coating in DRIA 1200 equipment of 50kg of sugar-containing chewing gum cores with peppermint taste.

5

Saccharose suspension	Amount of dosage	Smoothing out	Drying time	Drum
Dosage No.	g	time	sec.	
		sec.		rpm
1-2	500	45	300	11
3-12	900	45	400	11
13	600 + 222*	60	400	11
14-15	700	0	380	11
16-21	1000	0	380	11
22-34	1000	30	410	11
35-38	600	260	280	11
39	500	1500	290	11
40	wax powder 50g	300	300	8

* A 600g saccharose suspension + 222g peppermint oil.

[illegible]

Example 2

Coating in DRIA 1200 equipment of 50kg of sugar-free chewing gum cores with peppermint taste.

5

Sorbitol suspension Dosage No.	Amount of dosage g	Smoothing out time sec.	Drying time sec.	Drum rpm
1-2	400	0	250	11
3-5	700	15	300	11
6	700 + 200*	60	300	11
7-16	700	45	300	11
17-24	1000	45	350	11
25-26	700	240	240	11
27	wax powder 50g	360	360	8

* A 700g sorbitol suspension + 200g peppermint oil.

Example 3

Coating in tilted kettles of 2kg sugar-free chewing gum cores with a mixture of liquid eucalyptus, menthol, and anethol.

5

Sorbitol suspension Dosage No.	Amount of dosage g	Smoothing out time sec.	Drying time sec.	Number of revolutions rpm
1	20	120	120	50
2	20	90	120	50
3	20	60	60	50
4-9	30	30	90	50
10-11	30	30	120	50
12	20*	60	120	50
13	9.9 liquid flavour	10	0	50
14	20	40	0	50
15-16	20	5	120	50
17-22	30	60	120	50
23-26	40	30	120	50
27-33	30	60	120	50
34-35	20	120	240	50
36	wax powder 2g	300	300	50

* A sorbitol suspension with 3.5% aspartame and 7.5% acesulfame K.

Example 4

Coating in DRIA 1200 equipment of 50kg sugar-containing chewing gum cores with peppermint oil encapsulated in a 3:1 mixture of hydrogenated rape oil and carnauba wax.

Saccharose suspension	Amount of dosage g	Smoothing out time sec.	Drying time sec.	Drum rpm
Dosage No.				
1-2	500	45	300	11
3-12	900	45	400	11
13	400	10	0	11
14	400* powder	60	0	11
15-16	700	0	380	11
17	400	10	0	11
18	400* powder	60	0	11
19-20	700	0	380	11
21-24	1000	0	380	11
25-37	1000	30	410	11
38-41	700	260	280	11
42	500	1500	290	11
43	wax powder 50g	300	300	8

* A powder with a flavour concentration of 28%.

Example 5

Coating in DRIA 1200 equipment of 50kg sugar-free chewing gum cores with peppermint oil encapsulated in a 3:1 mixture of hydrogenated rape oil and carnauba wax.

Sorbitol suspension Dosage No.	Amount of dosage g	Smoothing out time sec.	Drying time sec.	Drum rpm
1-2	400	0	250	11
3-5	700	15	300	11
6	350	10	0	11
7	360* powder	60	0	11
8-9	700	10	300	11
10	350	10	0	11
11	360* powder	60	0	11
12-13	700	10	300	11
14-18	700	45	300	11
19-26	1000	45	350	11
27-28	700	240	240	11
29	wax powder 50g	360	360	8

* A powder with a flavour concentration of 28%.

Example 6

Coating in tilted round kettles of 2kg sugar-free chewing gum cores with peppermint oil encapsulated in silica.

5

Sorbitol suspension Dosage No.	Amount of dosage g	Smoothing out time sec.	Drying time sec.	Number of revolutions rpm
1	20	120	120	50
2	20	90	120	50
3	20	60	60	50
4-9	30	30	90	50
10-11	30	30	120	50
12	20*	60	120	50
13	20	10	0	50
14	17**powder	40	0	50
15-16	20	5	120	50
17-19	30	60	120	50
20-28	40	30	120	50
29-33	30	60	120	50
34-35	20	120	240	50
36	wax powder 2g	300	300	50

* A sorbitol suspension with 2.75% aspartame.

** A powder with a flavour concentration of 50%.

Example 7

Coating in tilted kettles of 2kg sugar-free chewing gum cores with peppermint oil encapsulated in gelatine.

5

Sorbitol suspension Dosage No.	Amount of dosage g	Smoothing out time sec.	Drying time sec.	Number of revolutions rpm
1	20	120	120	50
2	20	90	120	50
3	20	60	60	50
4-9	30	30	90	50
10-11	30	30	120	50
12	20*	60	120	50
13	20	10	0	50
14	17**powder	40	0	50
15-16	20	5	120	50
17-18	30	60	120	50
19	20	10	0	50
20	17**powder	40	0	50
21-22	20	5	120	50
23-24	30	60	120	50
25-28	40	30	120	50
29-35	30	60	120	50
36-37	20	120	240	50
38	wax powder 2g	300	300	50

* A sorbitol suspension with 2.75% aspartame.

** A powder with a flavour concentration of 25%.

Example 8

Coating in tilted kettles of 2kg sugar-free chewing gum cores with a mixture of eucalyptus, menthol, and anethol, encapsulated in a 3:1 mixture of hydrogenated rape oil and carnauba wax.

Sorbitol suspension Dosage No.	Amount of dosage g	Smoothing out time sec.	Drying time sec.	Number of revolutions rpm
1	20	120	120	50
2	20	90	120	50
3	20	60	60	50
4-9	30	30	90	50
10-11	30	30	120	50
12	20*	60	120	50
13	20	10	0	50
14	40**powder	40	0	50
15-16	20	5	120	50
17-18	30	60	120	50
19	20	10	0	50
20	40**powder	40	0	50
21-22	20	5	120	50
23-24	30	60	120	50
25-28	40	30	120	50
29-35	30	60	120	50
36-37	20	120	240	50
38	wax powder 2g	300	300	50

* A sorbitol suspension with 3.75% aspartame, and 7.5% acesulfame K.

** A powder with a flavour concentration of 24.5%.

Example 9

Coating in tilted kettles of 2kg sugar-free chewing gum cores with a mixture of eucalyptus, menthol, and anethol, encapsulated in a 3:1 mixture of hydrogenated rape oil

5 and carnauba wax.

Sorbitol suspension Dosage No.	Amount of dosage g	Smoothing out time sec.	Drying time sec.	Number of revolutions rpm
1	20	120	120	50
2	20	90	120	50
3	20	60	60	50
4-9	30	30	90	50
10-11	30	30	120	50
12	20*	60	120	50
13	20	10	0	50
14	20**powder	40	0	50
15-16	20	5	120	50
17-18	30	60	120	50
19	20	10	0	50
20	20**powder	40	0	50
21-22	20	5	120	50
23-24	30	60	120	50
25-28	40	30	120	50
29-35	30	60	120	50
36-37	20	120	240	50
38	wax powder 2g	300	300	50

* A sorbitol suspension with 3.5% aspartame and 7.5% acesulfame K.

** A powder with a flavour concentration of 24.5%.

Example 10

Coating in tilted kettles of 2kg sugar-free chewing gum cores with a mixture of liquid eucalyptus, menthol, and anethol, as well as menthol encapsulated in gum arabic.

Sorbitol suspension Dosage No.	Amount of dosage g	Smoothing out time sec.	Drying time sec.	Number of revolutions rpm
1	20	120	120	50
2	20	90	120	50
3	20	60	60	50
4-9	30	30	90	50
10-11	30	30	120	50
12	20*	60	120	50
13	9.9 liquid flavour	10	0	50
14	20	40	0	50
15-16	20	5	120	50
17-18	30	60	120	50
19	20	10	0	50
20	7** powder	40	0	50
21-22	20	5	120	50
23-24	30	60	120	50
25-28	40	30	120	50
29-35	30	60	120	50
36-37	20	120	240	50
38	wax powder 2g	300	300	50

* A sorbitol suspension with 3.5% aspartame and 7.5% acesulfame K.

** A powder with a flavour concentration of 80%.

Example 11

Coating in tilted kettles of 2kg sugar-free chewing gum cores with a mixture of liquid eucalyptus, menthol, anethol, as well as ammonium chloride encapsulated in a 3:1 mixture of hydrogenated rape oil and carnauba wax.

Sorbitol suspension Dosage No.	Amount of dosage g	Smoothing out time sec.	Drying time sec.	Number of revolutions rpm
1	20	120	120	50
2	20	90	120	50
3	20	60	60	50
4-9	30	30	90	50
10-11	30	30	120	50
12	20*	60	120	50
13	9.9 liquid flavour	10	0	50
14	20	40	0	50
15	20	5	120	50
16-17	30	60	120	50
18	20	10	0	50
19	40** powder	40	0	50
20-21	20	5	120	50
22	20	10	0	50
23	40** powder	40	0	50
24-25	20	5	120	50
26-27	30	60	120	50
28-30	40	30	120	50
31-37	30	60	120	50
38-39	20	120	240	50
40	wax powder 2g	300	300	50

*A sorbitol suspension with 3.5% aspartame and 7.5% acesulfame K.

**A powder with a ammonium chloride concentration of 30%.

Example 12

Coating in tilted kettles of 2kg sugar-free chewing gum cores with a mixture of liquid eucalyptus, menthol, and powdered anise, as well as naturally extract of black pepper

5 encapsulated in a 3:1 mixture of hydrogenated rape oil and carnauba wax.

Sorbitol suspension Dosage No.	Amount of dosage g	Smoothing out time sec.	Drying time sec.	Number of revolutions rpm
1	20	120	120	50
2	20	90	120	50
3	20	60	60	50
4-9	30	30	90	50
10-11	30	30	120	50
12	20	60	120	50
13	20	10	0	50
14	20* powder	40	0	50
15-16	20	5	120	50
17-18	30	60	120	50
19	10 liquid flavour	10	0	50
20	20	40	0	50
21-22	20	5	120	50
23-24	30	60	120	50
25-28	40	30	120	50
29-35	30	60	120	50
36-37	20	120	240	50
38	wax powder 2g	300	300	50

* A powder of naturally extract of black pepper in a concentration of 20%.

Example 13

Coating in tilted kettles of 2kg sugar-free chewing gum cores with a mixture of liquid eucalyptus, menthol, and powered anise as well as naturally basil extract encapsulated in a 3:1 mixture of hydrogenated rape oil and carnauba wax.

Sorbitol suspension Dosage No.	Amount of dosage g	Smoothing out time sec.	Drying time sec.	Number of revolutions rpm
1	20	120	120	50
2	20	90	120	50
3	20	60	60	50
4-9	30	30	90	50
10-11	30	30	120	50
12	20	60	120	50
13	20	10	0	50
14	20* powder	40	0	50
15-16	20	5	120	50
17-18	30	60	120	50
19	10 liquid flavour	10	0	50
20	20	40	0	50
21-22	20	5	120	50
23-24	30	60	120	50
25-28	40	30	120	50
29-35	30	60	120	50
36-37	20	120	240	50
38	wax powder 2g	300	300	50

* A powder of naturally basil extract in a concentration of 14%.

Example 14

Coating in tilted kettles of 2kg sugar-free chewing gum cores with a mixture of liquid eucalyptus, menthol, and powdered anise, as well as naturally thyme extract encapsu-
5 lated in a 3:1 mixture of hydrogenated rape oil and carnauba wax.

Sorbitol suspension Dosage No.	Amount of dosage g	Smoothing out time sec.	Drying time sec.	Number of revolutions rpm
1	20	120	120	50
2	20	90	120	50
3	20	60	60	50
4-9	30	30	90	50
10-11	30	30	120	50
12	20	60	120	50
13	20	10	0	50
14	20* powder	40	0	50
15-16	20	5	120	50
17-18	30	60	120	50
19	10 liquid flavour	10	0	50
20	20	40	0	50
21-22	20	5	120	50
23-24	30	60	120	50
25-28	40	30	120	50
29-35	30	60	120	50
36-37	20	120	240	50
38	wax powder 2g	300	300	50

* A powder of naturally thyme extract in a concentration of 15%.

Example 15

Coating in tilted kettles of 2kg sugar-free chewing gum cores with a mixture of mixture of liquid fruit flavours (orange, lemon, and mango) as well as citric acid
5 encapsulated in a 3:1 mixture of hydrogenated rape oil and carnauba wax.

Sorbitol suspension Dosage No.	Amount of dosage g	Smoothing out time sec.	Drying time sec.	Number of revolutions rpm
1	20	120	120	50
2	20	90	120	50
3	20	60	60	50
4-9	30	30	90	50
10-11	30	30	120	50
12	20*	60	120	50
13	20	10	0	50
14	30** powder	40	0	50
15-16	20	5	120	50
17	20	10	0	50
18	30** powder	40	0	50
19-20	20	5	120	50
21	5.7 liquid flavour	10	0	50
22	20	40	0	50
23-24	20	5	120	50
25-26	30	60	120	50
27-30	40	30	120	50
31-37	30	60	120	50
39-40	20	120	240	50
41	wax powder 2g	300	300	50

* A sorbitol suspension with 7.5% aspartame.

** Encapsulated citric acid in a concentration of 35%.

Example 16

Coating in tilted kettles of 2kg sugar-free chewing gum cores with a mixture of liquid fruit flavours (orange, lemon, and mango) as well as ascorbic acid encapsulated in a 5 3:1 mixture of hydrogenated rape oil and carnauba wax.

Sorbitol suspension Dosage No.	Amount of dosage g	Smoothing out time sec.	Drying time sec.	Number of revolutions rpm
1	20	120	120	50
2	20	90	120	50
3	20	60	60	50
4-9	30	30	90	50
10-11	30	30	120	50
12	20*	60	120	50
13	20	10	0	50
14	30** powder	40	0	50
15-16	20	5	120	50
17	20	10	0	50
18	30** powder	40	0	50
19-20	20	5	120	50
21	5.7 liquid flavour	10	0	50
22	20	40	0	50
23-24	20	5	120	50
25-26	30	60	120	50
27-30	40	30	120	50
31-37	30	60	120	50
39-40	20	120	240	50
41	wax powder 2g	300	300	50

* A sorbitol suspension with 7.5% aspartame.

** Encapsulated ascorbic acid in a concentration of 60%.

Example 17

Coating in tilted kettles of 2kg sugar-free chewing gum cores with a mixture of mixture of liquid fruit flavours (orange, lemon, and mango) as well as cooling agent encapsulated in gum arabic.

Sorbitol suspension Dosage No.	Amount of dosage g	Smoothing out time sec.	Drying time sec.	Number of revolutions rpm
1	20	120	120	50
2	20	90	120	50
3	20	60	60	50
4-9	30	30	90	50
10-11	30	30	120	50
12	20*	60	120	50
13	20	10	0	50
14	20** powder	40	0	50
15-16	20	5	120	50
17	20	10	0	50
18	20	40	0	50
19-20	20	5	120	50
21	5.7 liquid flavour	10	0	50
22	20	40	0	50
23-24	20	5	120	50
25-26	30	60	120	50
27-30	40	30	120	50
31-37	30	60	120	50
39-40	20	120	240	50
41	wax powder 2g	300	300	50

* A sorbitol suspension with 7.5% aspartame.

** Encapsulated cooling agent, "Cooling Flavouring Powder" from International Flavours and Fragrances, Ltd., England, in a concentration of 20%.

Example 18

Coating in tilted kettles of 2kg sugar-free chewing gum cores with a mixture of liquid flavours (apple and cinnamon) as well as aspartame encapsulated in a 3:1 mixture of 5 hydrogenated rape oil and carnauba wax.

Sorbitol suspension Dosage No.	Amount of dosage g	Smoothing out time sec.	Drying time sec.	Number of revolutions rpm
1	20	120	120	50
2	20	90	120	50
3	20	60	60	50
4-9	30	30	90	50
10-11	30	30	120	50
12	20	60	120	50
13	20	10	0	50
14	25* powder	40	0	50
15-16	20	5	120	50
17-18	30	60	120	50
19	6.6 liquid flavour	10	0	50
20	20	10	0	50
21-22	20	40	120	50
23-24	30	5	120	50
25-28	30	30	120	50
29-35	20	60	120	50
36-37	30	120	240	50
38	wax powder 2g	300	300	50

* Encapsulated aspartame in a concentration of 10%.

Test Results

A number of sensory tests were carried out as documentation of the achieved effect by the use of active substances in solid form in the coating of a coated chewing gum.

5

The tests were carried out with 5 to 8 trained tasters per test. The coated chewing gum was served in tasteless plastic cups coded with a randomised three-figure number. There was a 3-minute-break between each product tested, and each product was tested twice.

10

The tests were carried out partly in the form of a measurement of the flavour release as a function of time (time intensity tests), in which the products were tested after 5, 15, 30, 45, 60, 75, 90, 105, 120, 135, 150, 165, 180, 240, 300, 420, and 540 seconds, partly in the form of determination of a taste profile, in which the products were tested in intervals; the initial phase : 0 - 1 minute, the intermediate phase 1 - 3 minute(s), and the end phase 3 - 4 minutes.

15

Test 1

- 20 A measurement was carried out of the flavour release as a function of time from a chewing gum coated according to Example 8, i.e. with a mixture of eucalyptus, menthol, and anethol encapsulated in fat and wax. The flavour release from this chewing gum was compared with a chewing gum coated according to Example 3, i.e. with liquid eucalyptus, menthol, and anethol. The result of the test appears from Fig.
- 25 1 which shows that the use of encapsulated flavour in the coating layer partly results in an extremely high taste onset (taste explosion) during the first 60 seconds, and partly enhances the taste in all chewing phases.

Test 2

30

In this test, measurement of the flavour release as a function of time by the use of the same amount of eucalyptus/menthol/anethol flavour in liquid form (Example 3) and encapsulated in fat and wax (Example 9), respectively, was carried out. The result of the test appears from Fig. 2, which shows that the use of active substance in solid

form provides a strong taste explosion in the initial phase, and a significantly enhanced effect in the first 4-5 minutes can be observed.

Test 3

5

In this test, the effect of addition of menthol encapsulated in gum arabic to the coating of a chewing gum coated with liquid eucalyptus, menthol, and anethol, cf. Example 10, was examined and compared with a chewing gum coated according to Example 3, i.e. only with liquid eucalyptus, menthol, and anethol.

10

The result of the test is shown in Fig. 3 which shows that addition of encapsulated menthol causes a strong taste explosion in the initial phase and an enhanced taste effect in all the chewing phases.

15 Test 4

A stability test was carried out of a chewing gum coated in accordance with Example 18, i.e. coated with apple/cinnamon flavour as well as aspartame encapsulated in fat and wax. By way of comparison, a corresponding chewing gum in which the aspar-

20

tame was non-encapsulated was tested.

The result of the test is shown in Fig. 4 which shows that the chewing gum containing non-encapsulated aspartame loses its stability already after approx. 30 days after coating since it develops a bitter taste. The lack of stability is probably due to a reaction between aspartame and aldehyde-containing flavours. In a corresponding chewing gum with encapsulated aspartame in the coating no change in the taste is observed even after 90 days.

25

Thus, encapsulation of aspartame has a strong stability-improving effect

30

Test 5

A test was carried out with chewing gum coated according to Example 15, i.e. with a mixture of liquid fruit flavours (orange, lemon, and mango) as well as citric acid

encapsulated in fat and wax in order to determine the taste profile in the initial phase. By way of comparison, a taste profile was recorded for a corresponding chewing gum coated with the same fruit flavours (orange, lemon, and mango), but without encapsulated citric acid in the coating layer. The result of the test is shown in Fig. 5.

5

As will be apparent, a chewing gum with citric acid has a larger taste intensity and stronger citric notes than a corresponding product without citric acid.

Test 6

10

A test was carried out in order to determine the taste profile in the initial phase, the intermediate phase, and the end phase, respectively, of a chewing gum coated according to Example 17, i.e. with a mixture of liquid fruit flavours (orange, lemon, and mango) and with and without cooling flavour encapsulated in gum arabic. The result of the test is shown in Figs. 6, 7, and 8 which show that the chewing gum with the cooling agent has a larger taste intensity and stronger citric notes in the initial phase. As is apparent from Figs. 7 and 8, this tendency is maintained in the intermediate phase and in the end phase as well in spite of the fact that the cooling agent was placed in the coating layer only.

15
20

Thus, the chewing gum according to the invention shows an increased effect of the active substance in all the chewing phases.

Test 7

25

In this test the taste profile of a chewing gum coated according to Example 14, i.e. with a mixture of liquid eucalyptus, menthol, and powdered anise as well as natural thyme extract encapsulated in fat and wax, was determined.

30 The use of encapsulated thyme provides the possibility of developing a chewing gum with an entirely new combination of tastes without having to observe the occurrence of discoloration of the coating layer by the use of liquid extract.

Test 8

In this test the taste profile of a chewing gum coated according to Example 12, i.e. with a mixture of liquid eucalyptus, menthol, and powdered anise as well as natural extract of black pepper encapsulated in fat and wax, was determined. The result of this test is shown in Figs. 12, 13, and 14. In the same way as in test 7, the possibility of creating new combinations of tastes without discoloration of the coating layer is achieved.

10 The invention being thus described, it will be obvious that it may be varied in many ways. Such variations are not to be regarded as deviations from the idea and the scope of the invention, and all such modifications as would be obvious to persons skilled in the art, are intended to be included within the scope of the following claims.

x 40

Amended claims

8 June 2000

1. A coated chewing gum comprising a core of chewing gum and a coating comprising a coating material and one or more active substance(s), characterised in that the active substance(s) is/are added in solid form and is/are selected among natural vegetable flavouring agents having a water content of less than 75% by weight, acids, and high potent sweeteners.
2. The coated chewing gum according to claim 1 wherein the natural vegetable flavouring agent is selected among fruits and herbs.
3. The coated chewing gum according to claim 2 wherein the natural vegetable flavouring agent is selected among coconut, grape fruit, orange, lime, lemon, mandarin, pineapple, strawberry, raspberry, mango, passion fruit, kiwi, apple, pear, peach, apricot, cherry, grapes, banana, cranberry, blueberry, black currant, red currant, gooseberry, and lingonberry thyme, basil, valerian, fennel, parsley, camomile, tarragon, lavender, dill, cumin, bergamot, sage, aloe vera, spearmint, peppermint, eucalyptus, and mixtures thereof.
4. The coated chewing gum according to claim 3 wherein the water content of the natural vegetable flavouring agent is less than 60%, preferable less than 40%, more preferred less than 30%, such as less than 25%.
5. The coated chewing gum according to claim 4 wherein the water content of the natural vegetable flavouring agent is less than 20% by weight, such as less than 15%, more preferred less than 10% such as between 1.5-7%, more preferred between 2-6%.
6. The coated chewing gum according to any of claims 1-5 wherein the natural vegetable flavouring agent is freeze-dried.
7. The coated chewing gum according to any of claims 1-6 wherein the natural vegetable flavouring agent is in the form of a powder, slices or pieces or combinations thereof.

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ART 34 ANDT

8. The coated chewing gum according to claim 7 wherein the natural vegetable flavouring agent is in a form where the particle size is less than 3mm, such as less than 2mm, more preferred less than 1mm, calculated as the longest dimension of the particle.
- 5 9. The coated chewing gum according to claim 7 wherein the natural vegetable flavouring agent is in a form where the particle size is from 3µm to 2mm, such as from 4µm to 1mm.
- 10 10. The coated chewing gum according to any of claims 1-9 wherein the natural vegetable flavouring agent comprises seeds from a fruit e.g. from strawberry, blackberry and raspberry, and which seeds are substantially intact.
11. The coated chewing gum according to any of the preceding claims wherein the natural vegetable flavouring agent also provides the gum formulation with natural colour.
- 15 12. The coated chewing gum according to claim 1, characterised in that the natural vegetable flavour is selected among peppermint, periwinkle, eucalyptus, spearmint, anethol, menthol, powdered anise, and fruit flavours such as orange, lemon, mango, pineapple, lime, strawberry, cherry, black currant, blueberry,
- 20 13. The coated chewing gum according to claim 1, characterised in that the acids are selected among citric acid, malic acid, tartaric acid, lactic acid, and ascorbic acid.
- 25 14. The coated chewing gum according to claim 1, characterised in that the sweeteners are selected among aspartame, acesulfame K, saccharin, cyclamate, neohesperidine, thaumatin, glycyrrhizin, and salts thereof, monellin, sucralose, and alitame.
- 30 15. The coated chewing gum according to claim 1, characterised in that the functional substances are selected among vitamins, "cooling agents", flavour enhancers, and pharmaceuticals in the coating such as the vitamins A, B, C, D, and E, enzymes, nicotine, caffeine, acetylsalicylic acid, chlorhexidine, [zinc compounds], and antihistamines.

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AMENDED SHEET

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3
16. The coated chewing gum according to any of the preceding claims wherein the active substance(s) is/are in an encapsulated form.

17. The coated chewing gum according to any of the preceding claim[s] 16
5 wherein the encapsulated active substance is encapsulated in one or more material(s) selected among fatty substances, waxes, gelatine, gum arabic, starch, cellulose, cellulose derivatives, shellac, polyvinyl acetate, polyethylene, casein, zein, B cyclo-dextrine, silica, yeast cells, and a mixture of the above encapsulation materials, preferably a mixture of fatty substances and carnauba wax.

10

18. The coated chewing gum according to any of claims 1-17, characterised in that the coating additionally comprises one or more liquid active substance(s).

19. The coated chewing gum according to any of the preceding claims further
15 comprising a flavour [is] selected among natural, naturally identical or synthetic flavours, and plant extracts.

20. The coated chewing gum according to claim 19, characterised in that the plant extracts are selected among extracts of liquorice, coffee, tea, herbs such as
20 sage, thyme, basil, bergamot, balm, valerian, camomile, lavender, aloe vera, and spices such as pepper, cinnamon, capsicum, paprika, tarragon, fennel, mustard, dill, caraway, parsley, and tomato.

21. The coated chewing gum according to any of the preceding claims further
25 comprising a salt.

22. The coated chewing gum according to claim 21, characterised in that the salts are selected among sodium chloride, potassium chloride, ammonium chloride, sodium bicarbonate, and carbamide.

30

23. A method for the preparation of a coated chewing gum according to any of claims 1-22, characterised in that it comprises the following steps:

- 35
- 1) preparation of a core of chewing gum in a manner known per se,
 - 2) preparation of a coating suspension, also in a manner known per se,
 - 3) application of the coating suspension onto the cores of chewing gum in a manner known per se,

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- 4) Applying on the coating of one or more active substance(s) selected from 1-22 in solid form in one or more increment(s) after the application of the coating suspension, and optionally repeating step 3) and 4)
- 5
- 5) optionally, application of one or more liquid active substance(s) in one or more increment(s) between the applications of the coating suspension,
- 6) optionally, finally application of a surface layer.
- 10
24. The method according to claim 23, characterised in that the coating suspension comprises an aqueous solution of a sugar, a sugar alcohol, an artificial sweetener or mixtures thereof.
- 15
25. The method according to claim 24, characterised in that the coating suspension comprises an aqueous solution of one or more constituent(s) selected among saccharose, dextrose, sorbitol, xylitol, tagatose, mannitol, maltitol, isomalt, aspartame, acesulfame K, saccharine, cyclamate, taline, and neohesperidine.
- 20
26. The method according to any of claims 23-25, characterised in that the coating suspension is applied in approx. 2 to 90 increments, preferably in [approximately] 30-60 increments.
27. The method according to any of claims 23-26, characterised in that the active
- 25 substance(s) present in solid form is/are applied in 1 to 10 increment(s) between the dosages of the coating suspension, preferably 1-4 increment(s).
28. The use of one or more active substance(s) selected among natural vegetable flavour agents, high potent sweeteners and functional substances in solid form in the
- 30 coating of a coated chewing gum to achieve a fast onset of the effect.
29. The use of one or more active substance(s) selected among natural flavour agents, acids, high potent sweeteners, and functional substances in solid form in the coating of a coated chewing gum to achieve a better stability of the active
- 35 substance.
30. The use of one or more active substance(s) selected among natural vegetable flavour agents, acids, high potent sweeteners, and functional substances in solid

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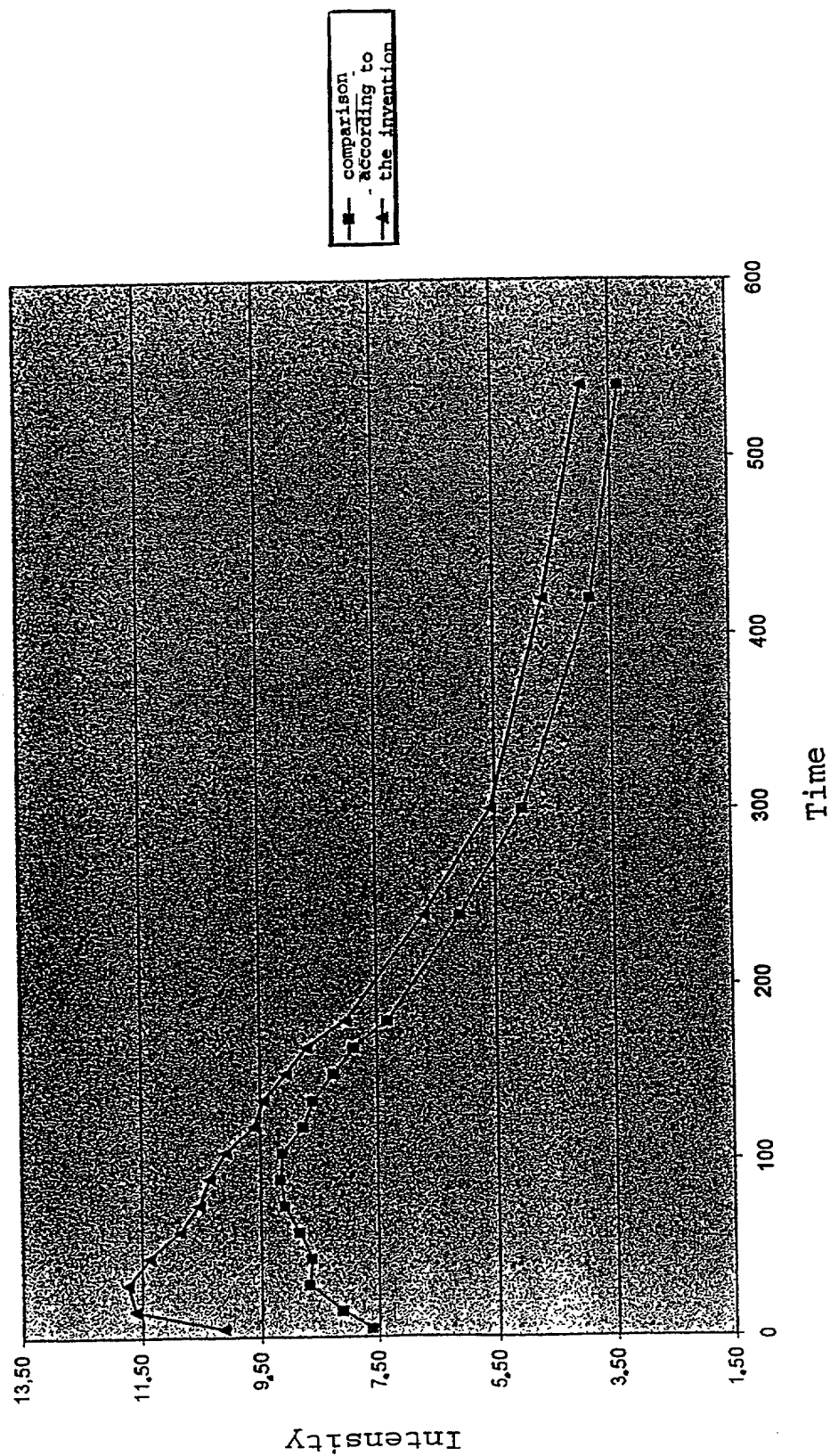
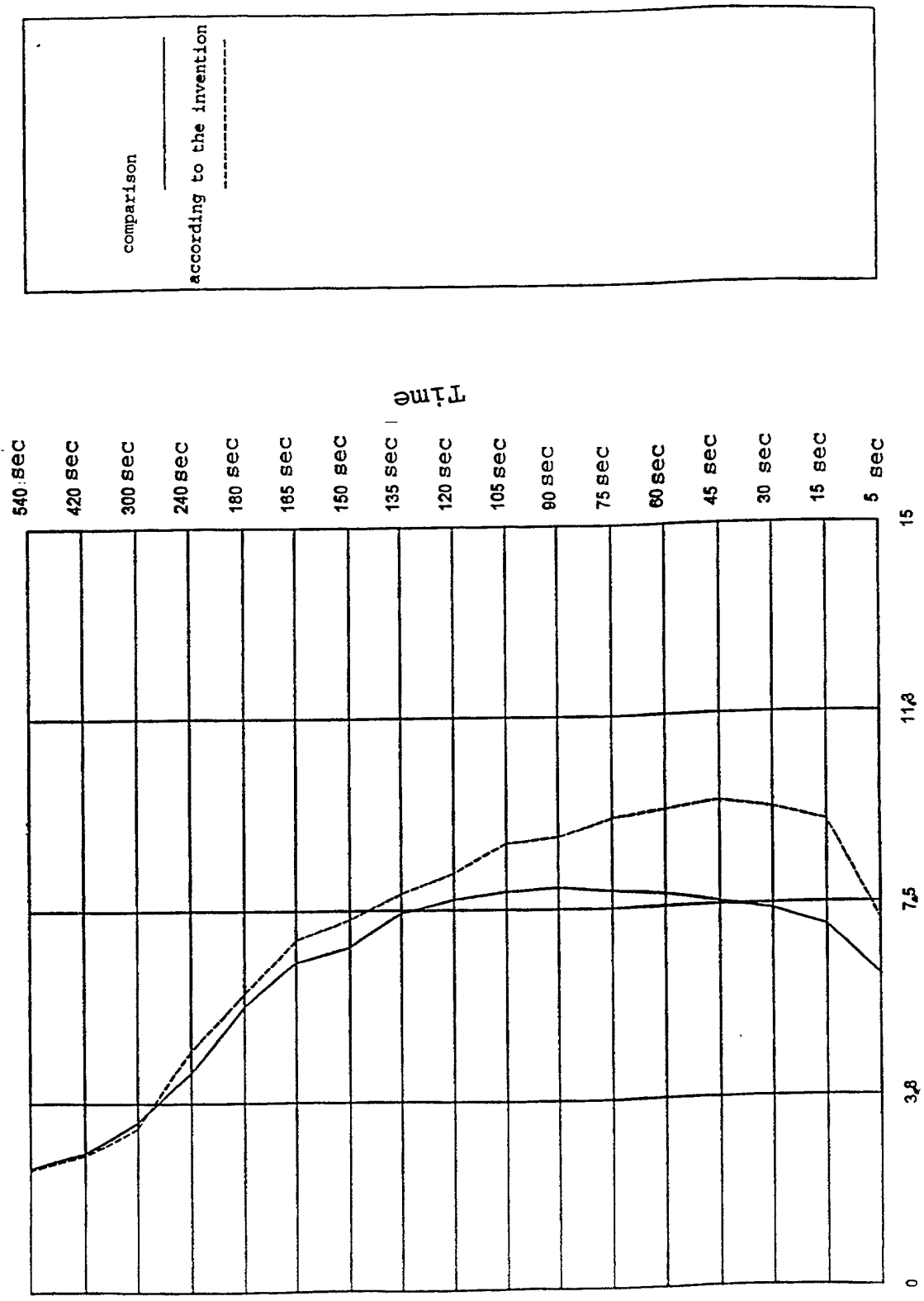


Fig. 1

FIG. 2

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Intensity
Fig. 2

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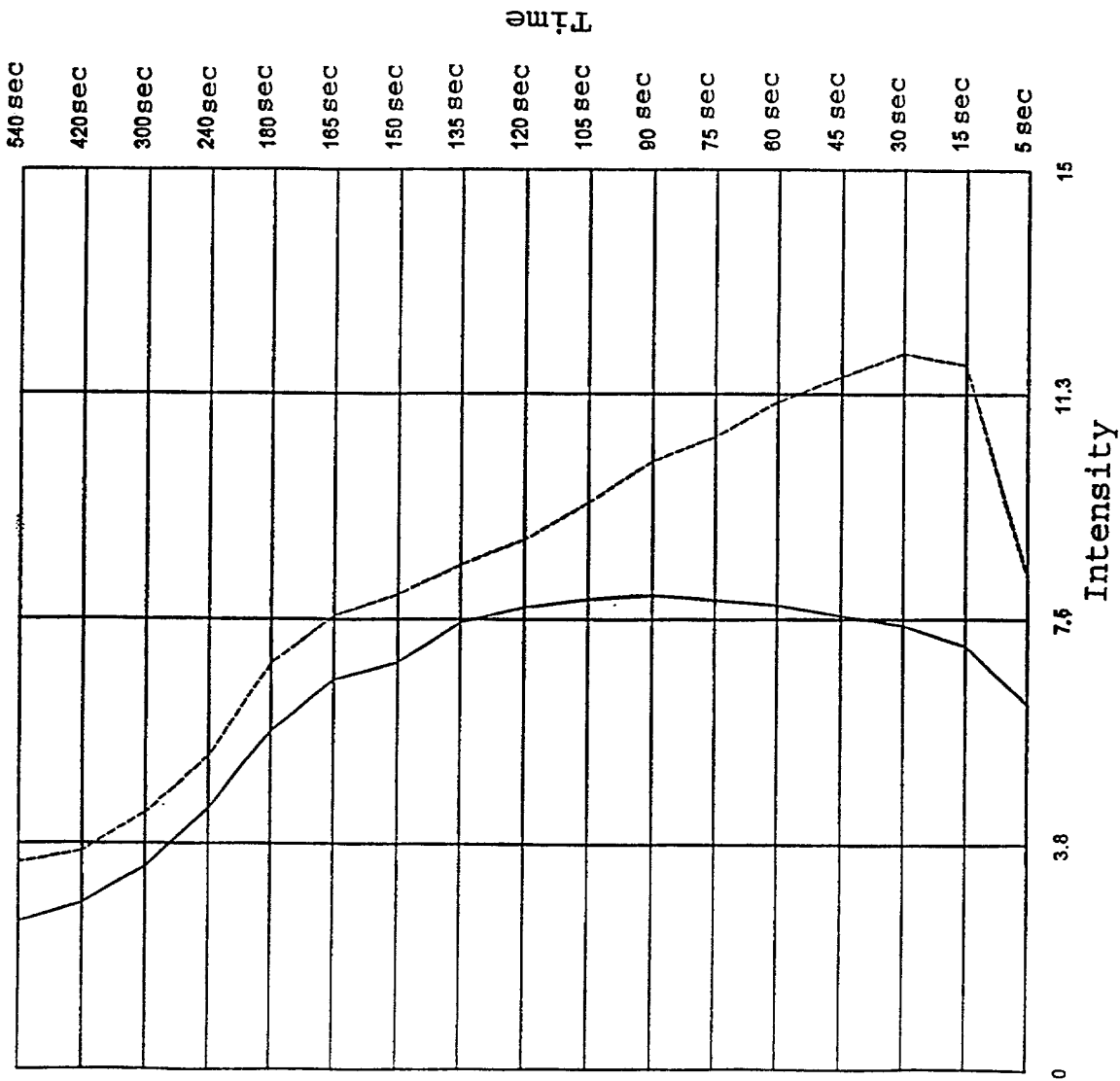
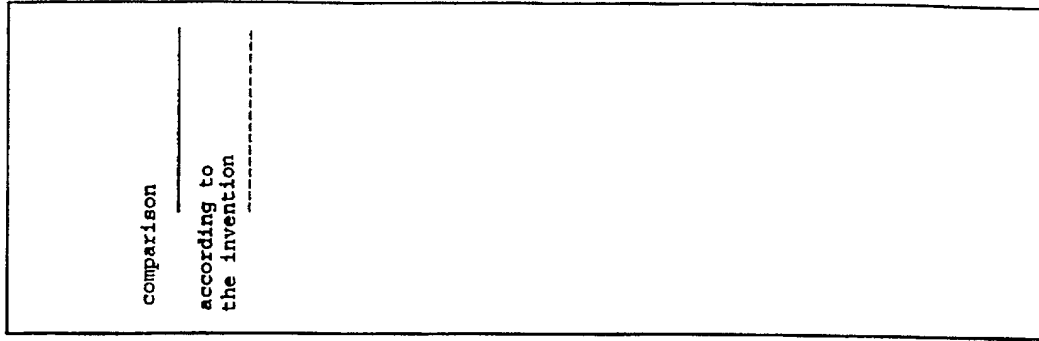


Fig. 3

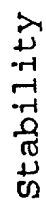


Fig. 4

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comparison _____
according to _____
the invention _____

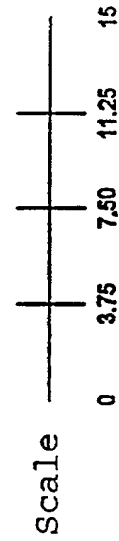
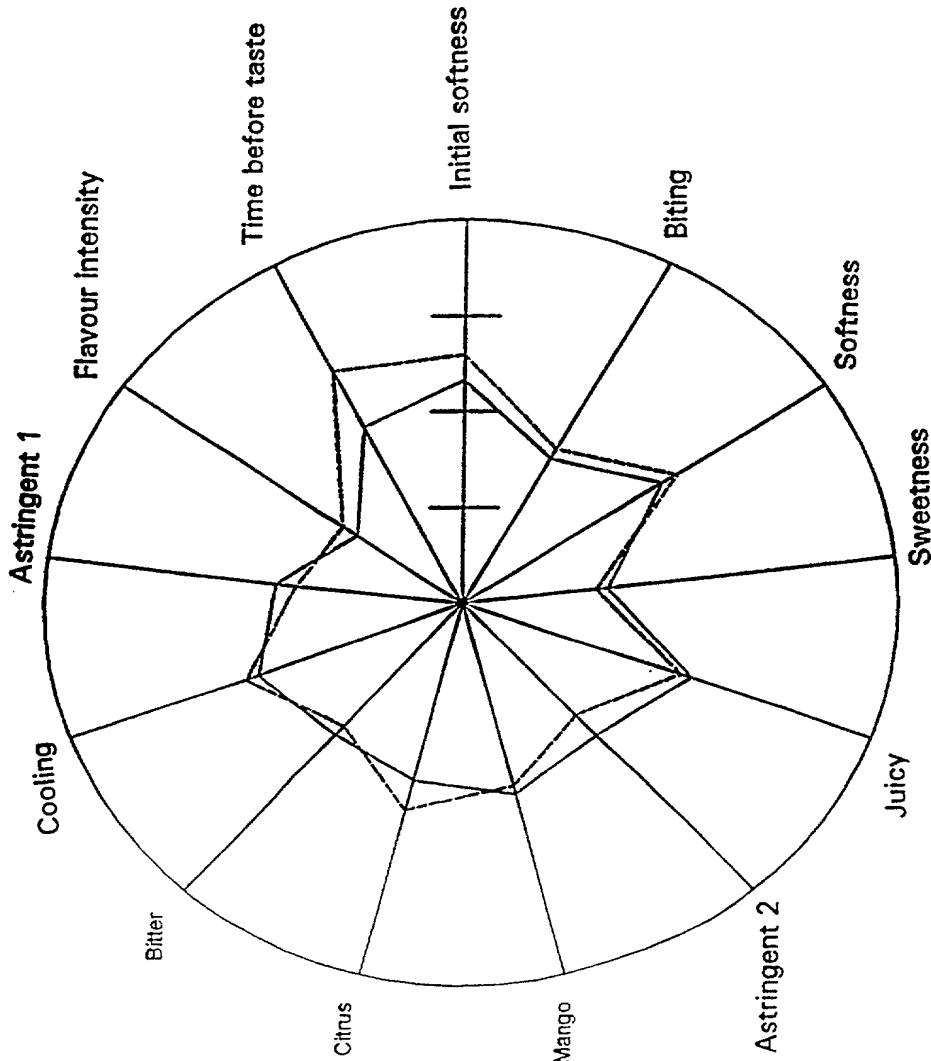
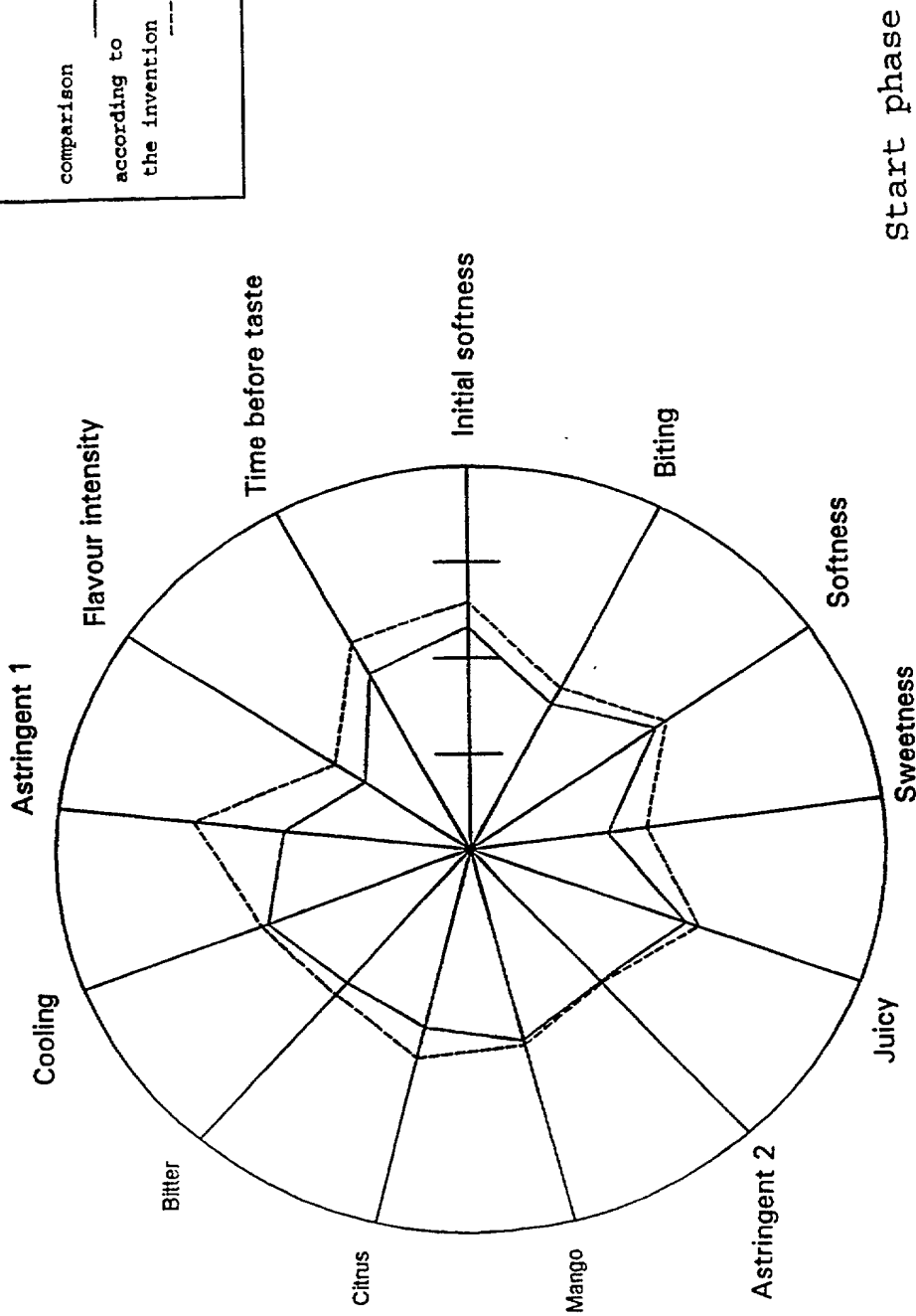
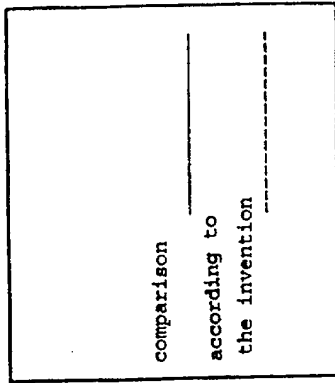


Fig. 5

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start phase

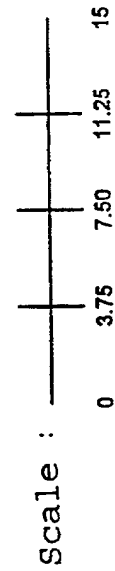


Fig. 6

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comparison _____
according to
the invention

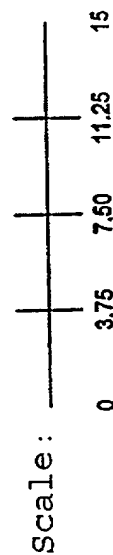
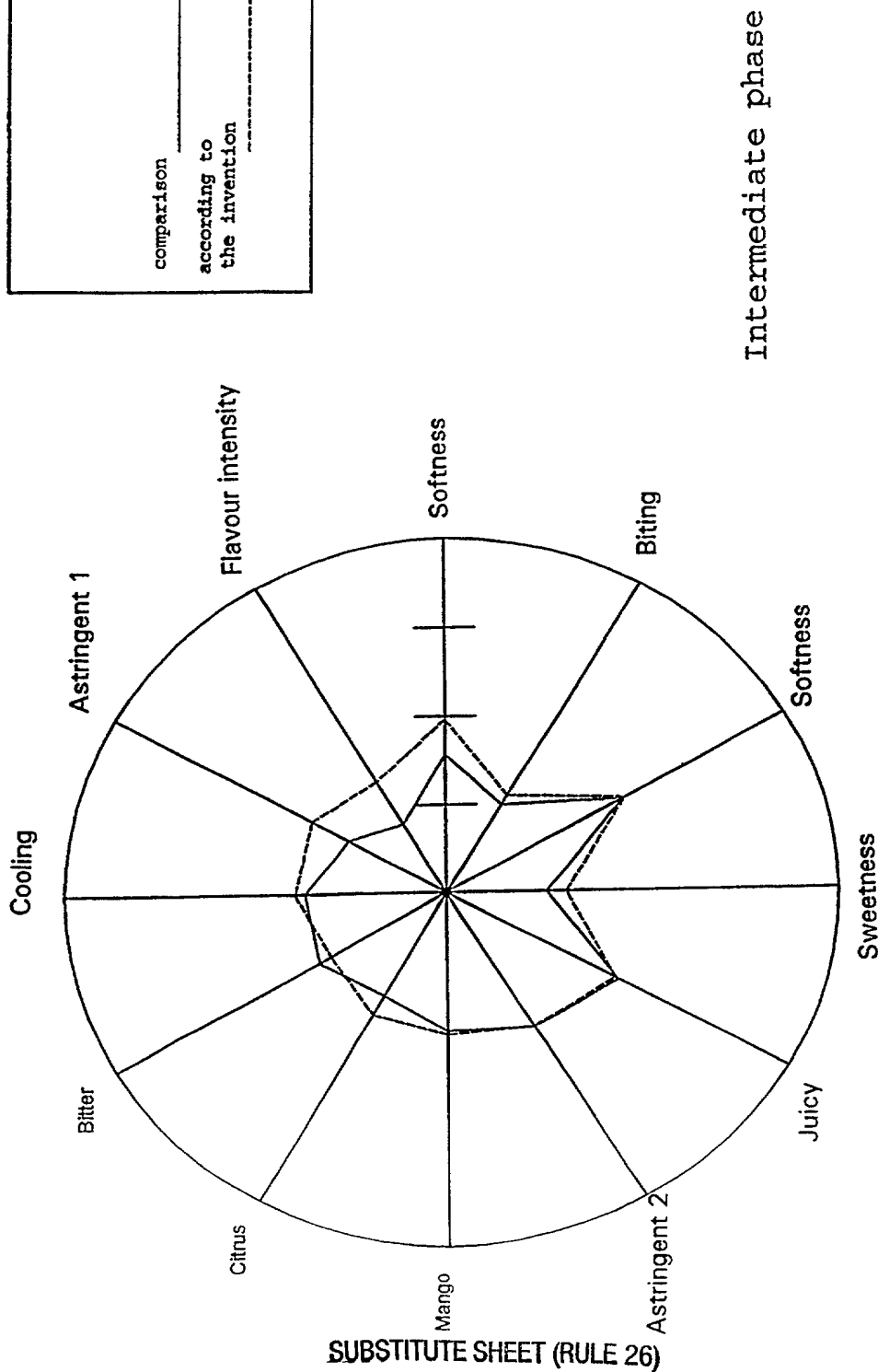


Fig. 7

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comparison _____
according to _____
the invention _____

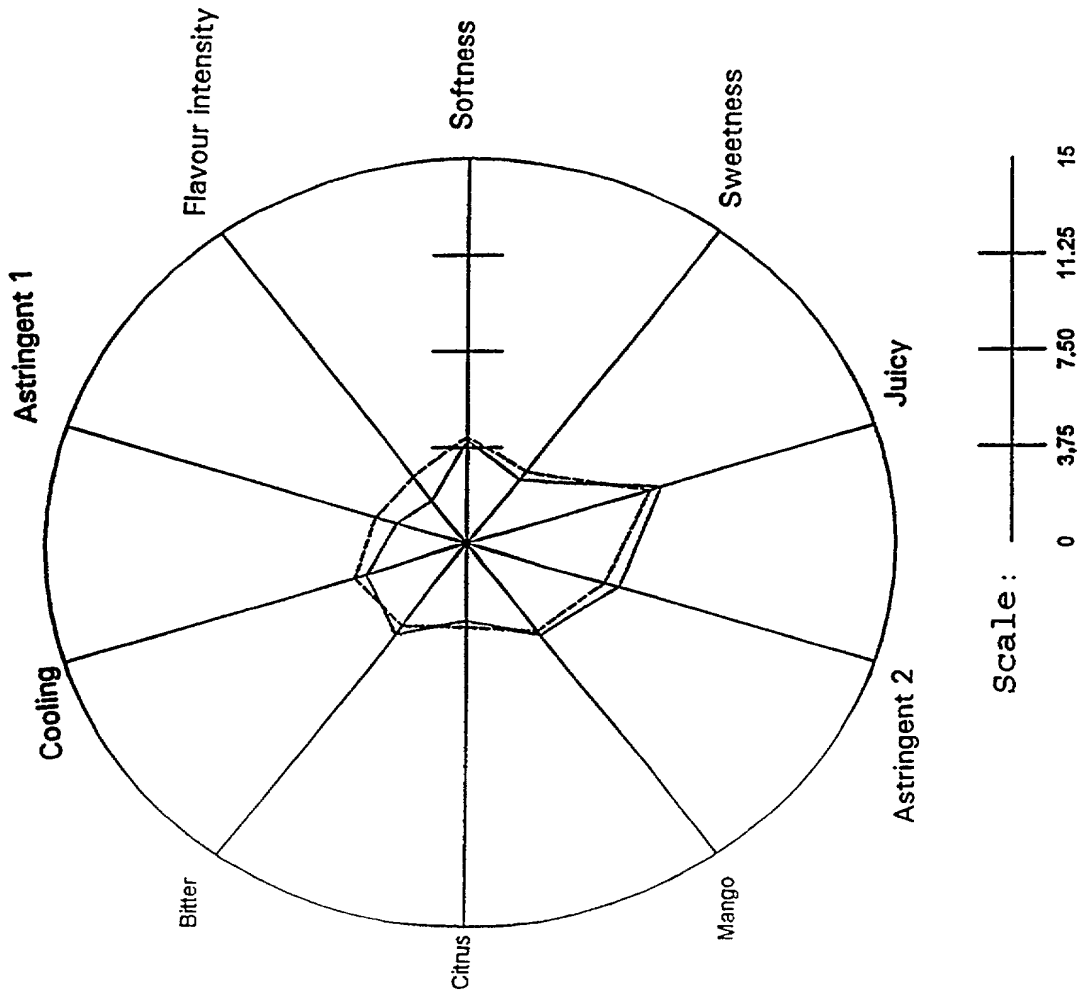
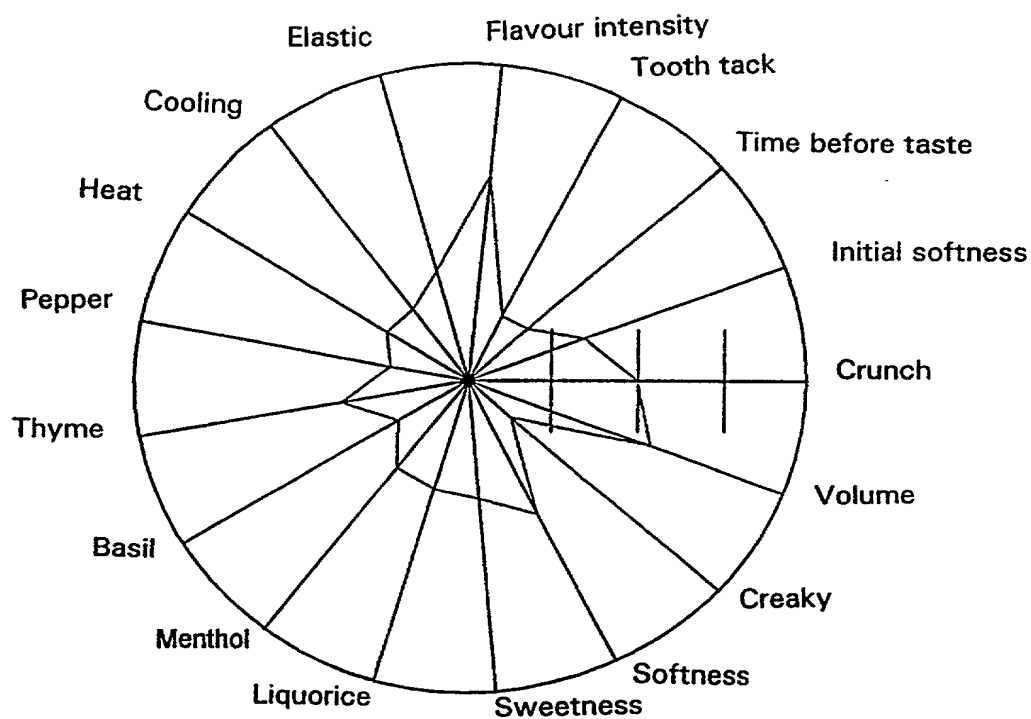


Fig. 8

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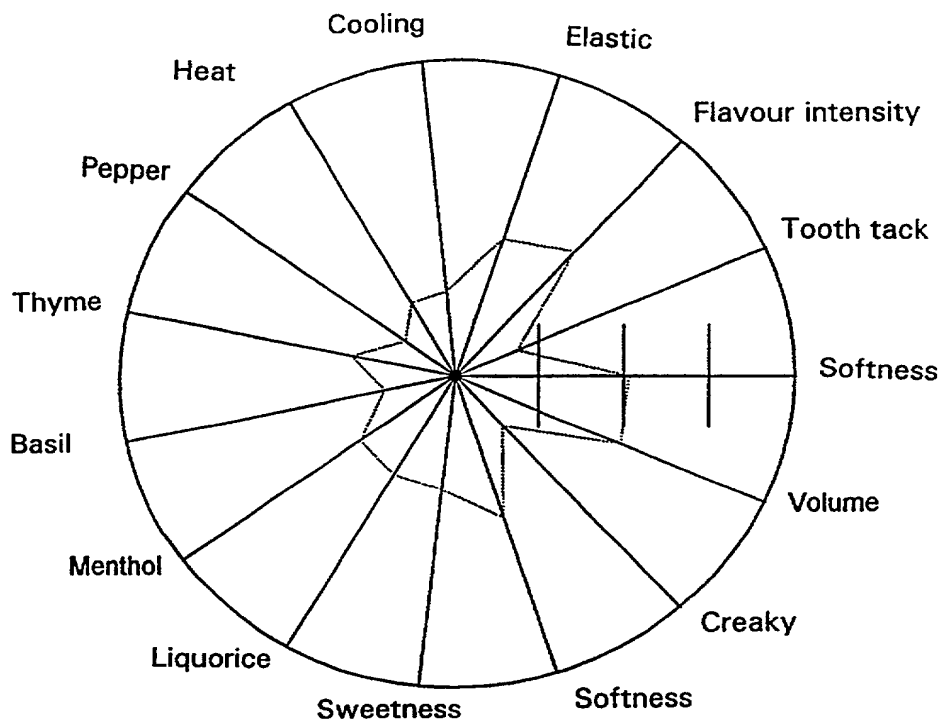


Scale : 0 3.75 7.50 11.25 15

Start phase

Fig. 9

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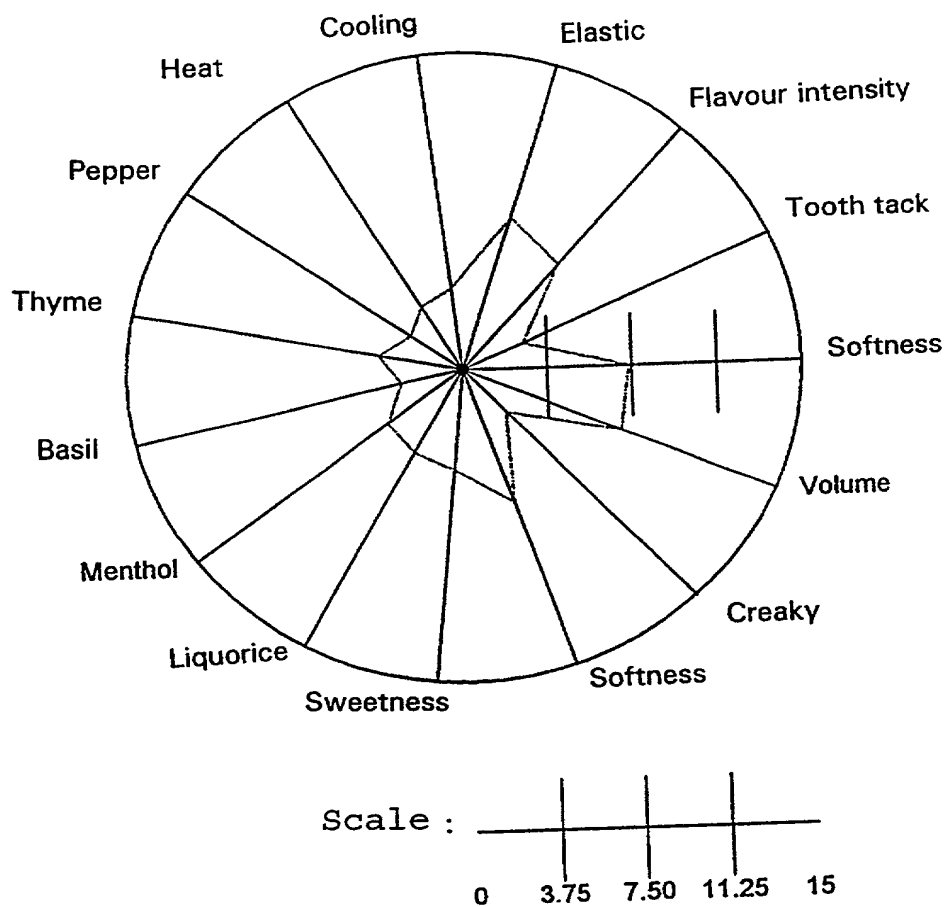


Scale : 0 3.75 7.50 11.25 15

Intermediate phase

Fig. 10

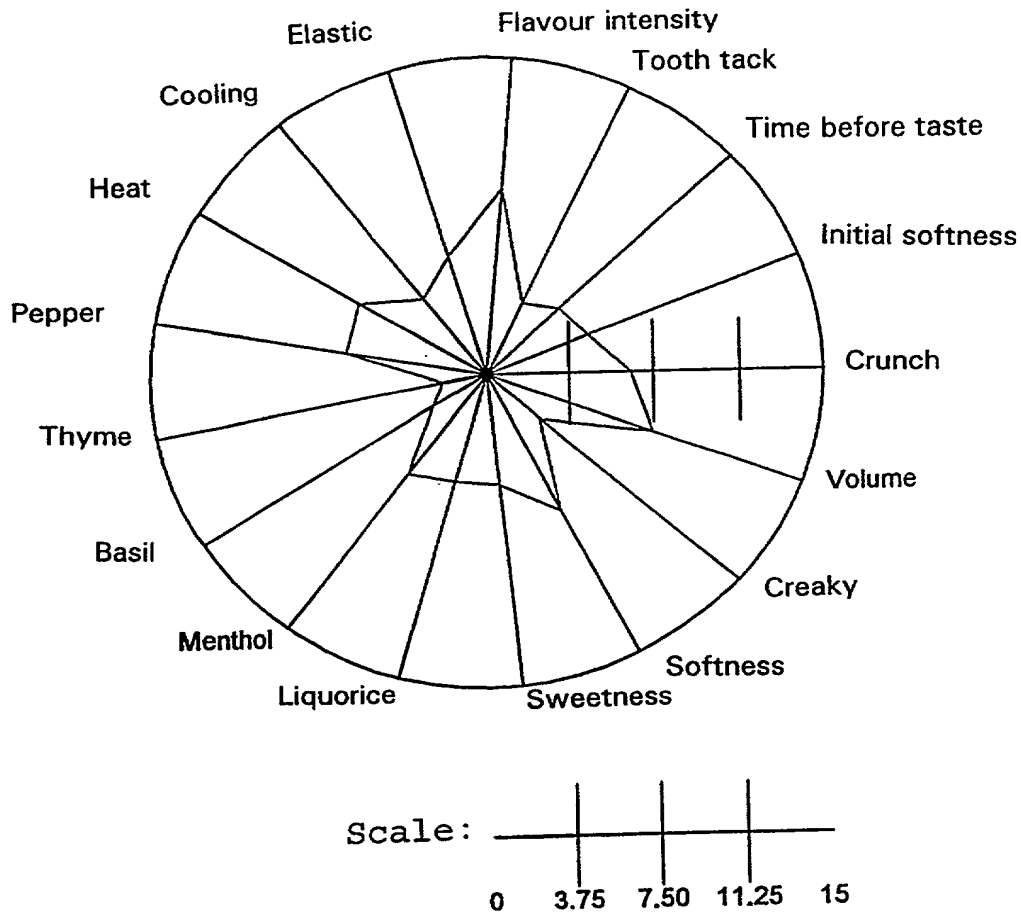
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End phase

Fig. 11

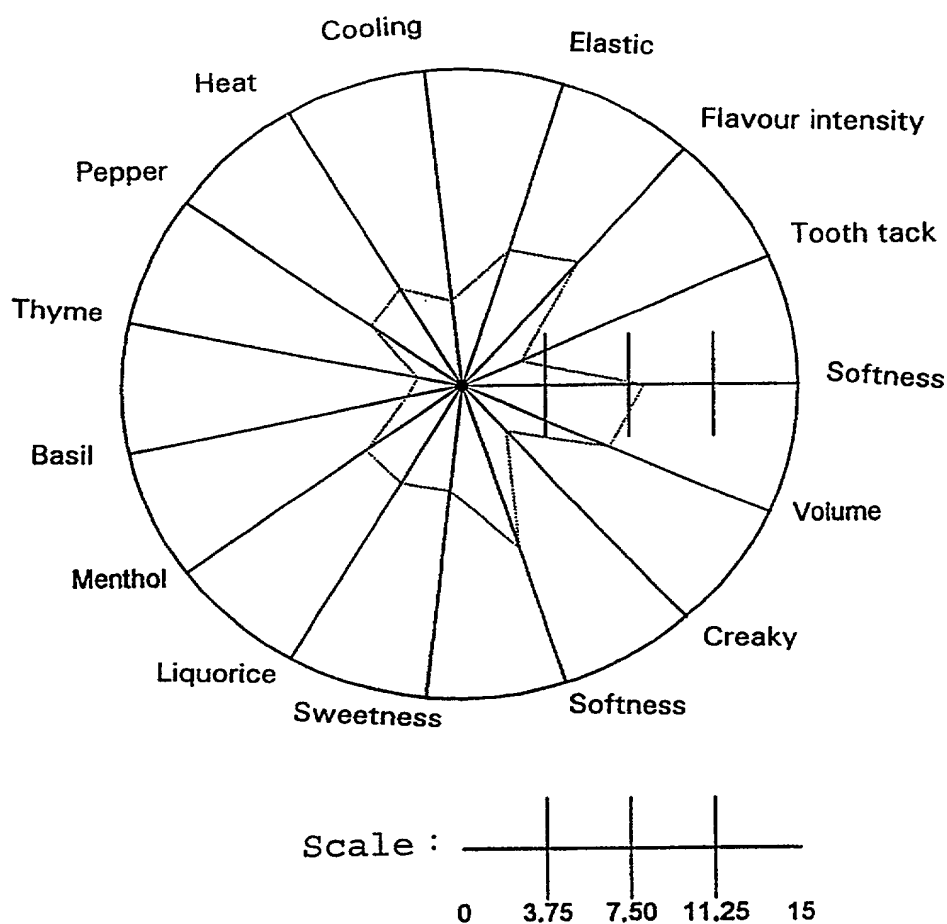
12/14



Start phase

Fig. 12

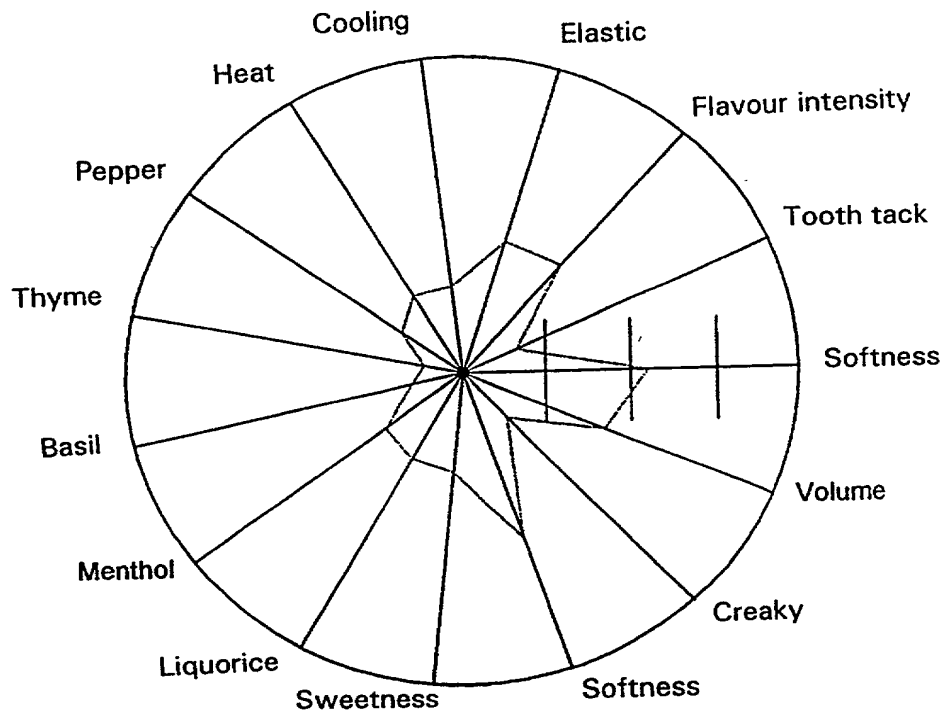
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Intermediate phase

Fig. 13

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Scale : 0 3.75 7.50 11.25 15

End phase

Fig. 14

26 MAR 2001
09/023425**Combined Declaration for Patent Application and Power of Attorney**

As a below-named inventor, I hereby declare that:

My residence, post office address and citizenship are as stated below next to my name; and that I believe I am the original, first and sole inventor (if only one name is listed below) or an original, first and joint inventor (if plural names are listed below) of the subject matter which is claimed and for which a patent is sought on the invention entitled

A COATED CHEWING GUM, A METHOD FOR PREPARATION THEREOF AND THE USE OF ONE OR MORE ACTIVE SUBSTANCES

the specification of which (check one)

- [] is attached hereto;
 [] was filed in the United States under 35 U.S.C. §111 on _____, as
 U.S. Appl. No. _____*; or
 [x] was/will be filed in the U.S. under 35 U.S.C. §371 by entry into the U.S. national stage of an international (PCT) application, PCT/DK99/00108; filed 3 March 1999, entry requested on 5 September 2000*; national stage application received U.S. Appl. No. _____*; §371/§102(e) date
 _____* (* if known)

and was amended on 5 September 2000 (if applicable).

(include dates of amendments under PCT Art. 19 and 34 if PCT)

I have reviewed and understand the contents of the above-identified specification, including the claims, as amended by any amendment referred to above; and I acknowledge the duty to disclose to the Patent and Trademark Office (PTO) all information known by me to be material to patentability as defined in 37 C.F.R. §1.56.

I hereby claim foreign priority benefits under 35 U.S.C. §§ 119 and 365 of any prior foreign application(s) for patent or inventor's certificate, or prior PCT application(s) designating a country other than the U.S., listed below with the "Yes" box checked and have also identified below any such application having a filing date before that of the application on which priority is claimed:

<u>0296/98</u>	<u>Denmark</u>	<u>4 March 1998</u>	[x]	[]
(Number)	(Country)	(Day Month Year Filed)	YES	NO
_____	_____	_____	[]	[]
(Number)	(Country)	(Day Month Year Filed)	YES	NO

I hereby claim the benefit under 35 U.S.C. §120 of any prior U.S. non-provisional application(s) or prior PCT application(s) designating the U.S. listed below, or under §119(e) of any prior U.S. provisional applications listed below, and, insofar as the subject matter of each of the claims of this application is not disclosed in such U.S. or PCT application in the manner provided by the first paragraph of 35 U.S.C. §112, I acknowledge the duty to disclose to the PTO all information as defined in 37 C.F.R. §1.56(a) which occurred between the filing date of the prior application and the national filing date of this application:

_____	_____	_____
(Application No.)	(Day Month Year Filed)	(Status: patented, pending, abandoned)
_____	_____	_____
(Application No.)	(Day Month Year Filed)	(Status: patented, pending, abandoned)
_____	_____	_____
(Application No.)	(Day Month Year Filed)	(Status: patented, pending, abandoned)

As a named inventor, I hereby appoint the following registered practitioners to prosecute this application and to transact all business in the Patent and Trademark Office connected therewith:

All of the practitioners associated with Customer Number 001444

Direct all correspondence to the address associated with Customer Number 001444; i.e.,

BROWDY AND NEIMARK, P.L.L.C.
624 Ninth Street, N.W.
Washington, D.C. 20001-5303
(202) 628-5197

The undersigned hereby authorizes the U.S. Attorneys or Agents appointed herein to accept and follow instructions from Ploughman, Vingtoft & Partners as to any action to be taken in the U.S. Patent and Trademark Office regarding this application without direct communication between the U.S. Attorneys or Agents and the undersigned. In the event of a change of the persons from whom instructions may be taken, the U.S. Attorneys or Agents appointed herein will be so notified by the undersigned.

Title: A COATED CHEWING GUM, A METHOD FOR PREPARATION THEREOF AND ...

U.S. Application filed _____, Serial No. _____

PCT Application filed _____, Serial No. _____

I hereby further declare that all statements made herein of my own knowledge are true and that all statements made on information and belief are believed to be true; and that these statements were made with the knowledge that willful false statements and the like so made are punishable by fine or imprisonment, or both, under 18 U.S.C. §1001 and that such willful false statements may jeopardize the validity of the application or any patent issued thereon.

FULL NAME OF FIRST INVENTOR <u>Bronislaw-Jan STAHL</u>		INVENTOR'S SIGNATURE <u>B. Stahl</u>	DATE
RESIDENCE <u>Vejle, Denmark</u>		CITIZENSHIP <u>Danish</u> <u>DKX</u>	
POST OFFICE ADDRESS <u>Magnoliavej 15, DK-7100 Vejle, Denmark</u>			
FULL NAME OF SECOND JOINT INVENTOR		INVENTOR'S SIGNATURE	DATE
RESIDENCE		CITIZENSHIP	
POST OFFICE ADDRESS			
FULL NAME OF THIRD JOINT INVENTOR		INVENTOR'S SIGNATURE	DATE
RESIDENCE		CITIZENSHIP	
POST OFFICE ADDRESS			
FULL NAME OF FOURTH JOINT INVENTOR		INVENTOR'S SIGNATURE	DATE
RESIDENCE		CITIZENSHIP	
POST OFFICE ADDRESS			
FULL NAME OF FIFTH JOINT INVENTOR		INVENTOR'S SIGNATURE	DATE
RESIDENCE		CITIZENSHIP	
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FULL NAME OF SIXTH JOINT INVENTOR		INVENTOR'S SIGNATURE	DATE
RESIDENCE		CITIZENSHIP	
POST OFFICE ADDRESS			
FULL NAME OF SEVENTH JOINT INVENTOR		INVENTOR'S SIGNATURE	DATE
RESIDENCE		CITIZENSHIP	
POST OFFICE ADDRESS			

ALL INVENTORS MUST REVIEW APPLICATION AND DECLARATION BEFORE SIGNING ALL ALTERATIONS MUST BE INITIALED AND DATED BY ALL INVENTORS PRIOR TO EXECUTION. NO ALTERATIONS CAN BE MADE AFTER THE DECLARATION IS SIGNED ALL PAGES OF DECLARATION MUST BE SEEN BY ALL INVENTORS